FLAREHAWK7

LUMBAR INTERBODY FUSION SYSTEM

INTEGRITY
IMPLANTS

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SYSTEM OVERVIEW **& INTENDED USE**

The core principles of successful fusion are widely recognized by spine surgeons: restoration of stability, minimization of neural and tissue disruption, and creation of an optimal fusion environment.

Integrity Implants designed the FlareHawk7 Interbody Fusion System to respect each of these principles without compromise.

FlareHawk7 permits concurrent expansion in height and width to restore disc height without sacrificing stability. It enters the disc space with a compact profile but maintains an open construction when expanded that enables significant graft delivery.

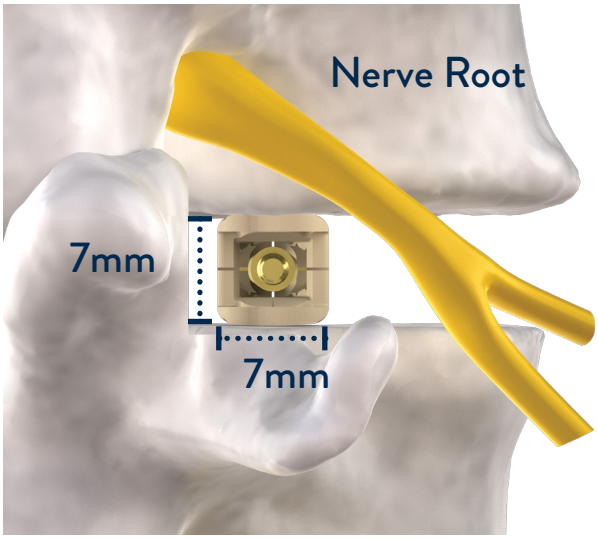
With FlareHawk7, advantages formerly exclusive to either expandable or monolithic devices are united for the first time.

This surgical technique applies to both TiHawk7 and FlareHawk7 Shells, although FlareHawk7 is specifically mentioned in the surgical steps.

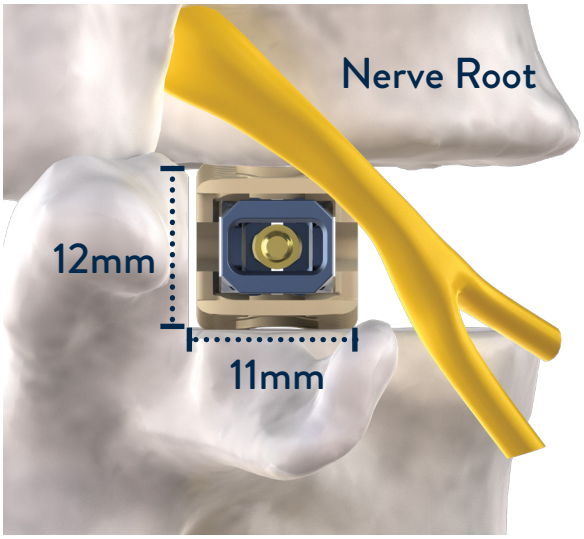
The FlareHawk® Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment.

Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk® system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.



Insertion Profile



Expanded Profile

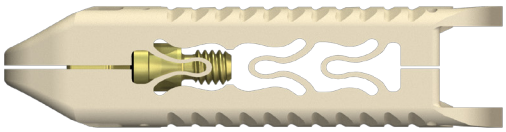
IMPLANT **OVERVIEW**

Each fully expanded FlareHawk7 device consists of two components: a Shim and a Shell. When the device is deployed, these components lock together to create one complete device. The dimensions of the final deployed device are determined by the dimensions of the selected Shim and Shell.

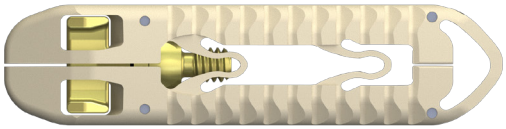
THE SHELL

FLAREHAWK7

The FlareHawk7 Shell is manufactured from a radiolucent polymer (PEEK). It contains an integrated titanium alloy Core that anchors the Inserter during Shim delivery and locks with the Shim when the Implant is deployed. There are ten tantalum markers embedded in the Shell, which enable radiographic verification of positioning and lock. Each Shell features a bulleted nose designed to facilitate ease of insertion, as well as directional teeth on its superior and inferior surfaces designed to resist expulsion by gripping the adjacent vertebral endplates. Shells are offered in Short and Tall options.



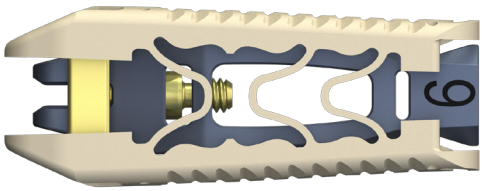
Lateral View Unexpanded



Axial View Unexpanded

TiHAWK7™

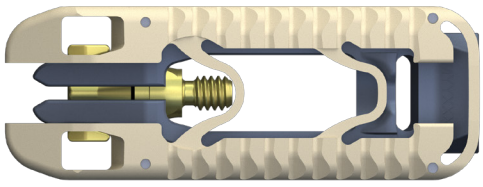
TiHawk7 Shells have an additional 0.5-micron thick layer of commercially pure titanium bonded to the surface of the PEEK. This thin layer is radiolucent and enables the TiHawk7 Shell to maintain the same properties as the FlareHawk7 Shell, but with a titanium surface.



Lateral View Expanded

THE SHIM

The Shim is manufactured from titanium alloy. It includes a split tip that locks with the Core when the Implant is deployed. All Shims are color-coded by size. Each Shim is marked with its lot number, its built-in lordosis, and the deployed height options that are possible when it is combined with either a Short or Tall Shell.



Axial View Expanded

LOCKING MECHANISMS

There are two locking mechanisms that keep the Shim and Shell together upon deployment.

- **Anterior Lock:** The Shim locks to the Core of the Shell.
- **Posterior Lock:** The Shim's Fins and the Shell's Posterior Locking Tabs create interference.

IMPLANT SIZE OPTIONS

The Implant size options are determined by the combination of the Shim and Shell. The Shell determines the insertion profile of the Implant, and its combination with the Shim determines final height and lordosis. The chart to the right and the table below show the insertion profiles, height, and lordosis options for each Shell.

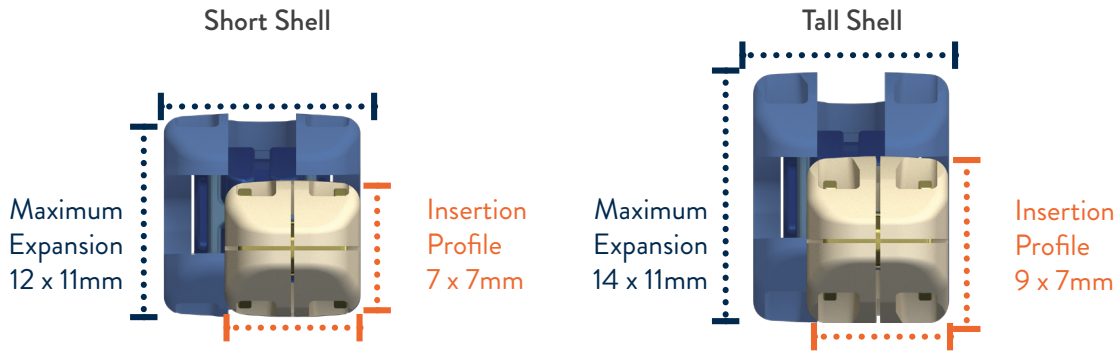
		Lordosis	
		0 Deg	6 Deg
Final Construct (H x W)	8 x 11mm	7 x 7mm	
	9 x 11mm	7 x 7mm	
	10 x 11mm	7 x 7mm	7 x 7mm
	11 x 11mm	7 x 7mm	7 x 7mm
	12 x 11mm	9 x 7mm	7 x 7mm
	13 x 11mm	9 x 7mm	9 x 7mm
	14 x 11mm	9 x 7mm	9 x 7mm

Insertion profiles

Both TiHawk7 and FlareHawk7 Shells are provided in the same sizes and are used in conjunction with the same Shims. FlareHawk7 will be specifically named throughout this technique, but the surgical steps apply to both FlareHawk7 and TiHawk7.

FlareHawk7 provides the surgeon with a wide range of height and lordosis options in 26mm and 30mm lengths. All Implants have an insertion profile of 7mm or 9mm high and 7mm wide. The "7" in FlareHawk7 is named from the insertion width of 7mm. All FlareHawk7 Implants insert at 7mm in width and expand to 11mm. The images below illustrate the insertion profiles and maximum expansion profiles of the FlareHawk7 Implants.

Shells (26 & 30mm)	Insertion Profile	Width Expansion	0° Height Range	6° Height Range
Short Shell	7mm H x 7mm W	11mm	8 – 11mm	10 – 12mm
Tall Shell	9mm H x 7mm W	11mm	12 – 14mm	13 – 14mm

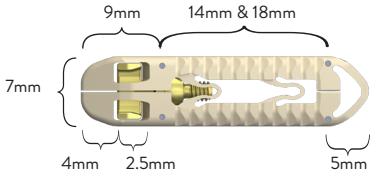


IMPLANT SPECS

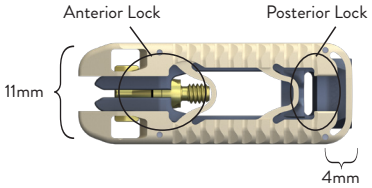
Constructs	Entry Profile (HxW)	Shell	Shim	Expanded Profile (Anterior HxW)	26mm Implants		30mm Implants	
					Posterior Height	Difference (A-P)	Posterior Height	Difference (A-P)
8mm 0 Deg	7x7mm	Short Shell	8 or 11, 0 Deg Shim	8x11mm	8mm	0mm	8mm	0mm
9mm 0 Deg	7x7mm	Short Shell	9 or 12, 0 Deg Shim	9x11mm	9mm	0mm	9mm	0mm
10mm 0 Deg	7x7mm	Short Shell	10 or 13, 0 Deg Shim	10x11mm	10mm	0mm	10mm	0mm
11mm 0 Deg	7x7mm	Short Shell	11 or 14, 0 Deg Shim	11x11mm	11mm	0mm	11mm	0mm
12mm 0 Deg	9x7mm	Tall Shell	9 or 12, 0 Deg Shim	12x11mm	12mm	0mm	12mm	0mm
13mm 0 Deg	9x7mm	Tall Shell	10 or 13, 0 Deg Shim	13x11mm	13mm	0mm	13mm	0mm
14mm 0 Deg	9x7mm	Tall Shell	11 or 14, 0 Deg Shim	14x11mm	14mm	0mm	14mm	0mm
10mm 6 Deg	7x7mm	Short Shell	10 or 12, 6 Deg Shim	10x11mm	8mm	2mm	7.5mm	2.5mm
11mm 6 Deg	7x7mm	Short Shell	11 or 13, 6 Deg Shim	11x11mm	9mm	2mm	8.5mm	2.5mm
12mm 6 Deg	7x7mm	Short Shell	12 or 14, 6 Deg Shim	12x11mm	10mm	2mm	9.5mm	2.5mm
13mm 6 Deg	9x7mm	Tall Shell	11 or 13, 6 Deg Shim	13x11mm	11mm	2mm	10.5mm	2.5mm
14mm 6 Deg	9x7mm	Tall Shell	12 or 14, 6 Deg Shim	14x11mm	12mm	2mm	11.5mm	2.5mm

AXIAL

Compressed



Expanded



LATERAL

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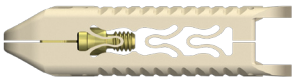
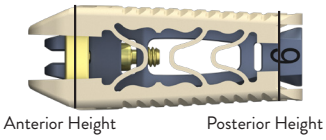
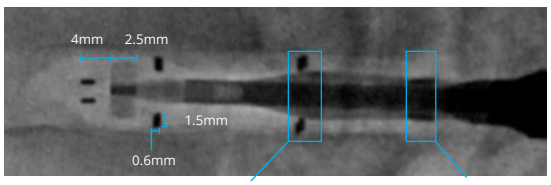


Expanded



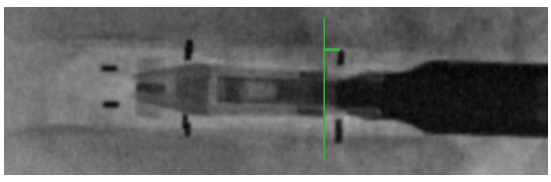
DIRECT LATERAL FLUOROSCOPIC VIEW

Compressed



Tantalum Markers (10 per Shell) — Locking Fins

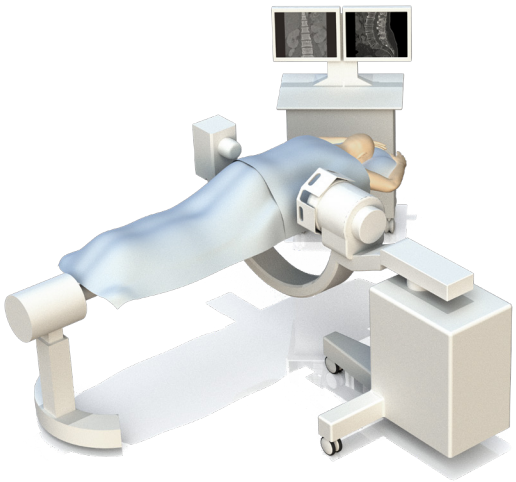
Expanded



Locking Fins anterior to the posterior Tantalum Markers = **Locked Implant**

SURGICAL **PREPARATION**

This surgical technique applies to both TiHawk7 and FlareHawk7 Shells, although FlareHawk7 is specifically mentioned in the surgical steps.



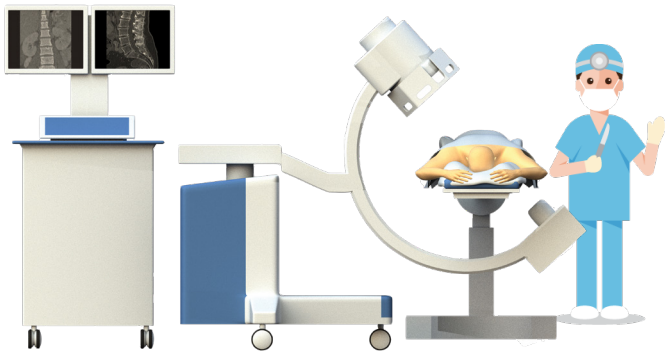
PATIENT POSITIONING

The patient is anesthetized and placed in an optimal position for the chosen surgical approach. The surgical region is sanitized, and an incision is made at the operative level(s) of the spine, continuing down to the target facet(s). Fluoroscopy or another imaging modality is used throughout the procedure for planning and to confirm proper implant placement and locking.

In order to obtain the contralateral oblique image for lock confirmation, the C-arm must be positioned to the opposite side of the TLIF being performed as shown in the image to the right.

ACCESS

Ensure the surgeon's preferred retractor system is available so that access to the operative level(s) may be gained. Use appropriate instruments, such as osteotomes, rongeurs, and burrs, to partially or completely remove the superior facet of the caudal vertebra and the inferior facet of the cephalad vertebra at the operative level(s) to create a unilateral, transforaminal space through which to access the disc.



C-arm positioned for lock confirmation

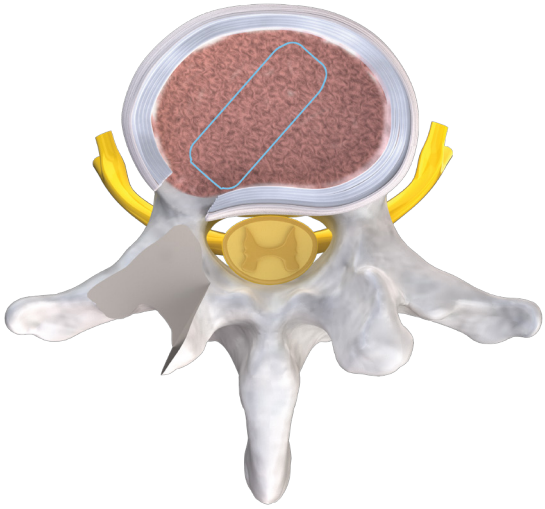
Expose the disc space using proper hemostatic technique. Use a nerve root retractor as required. Perform an annulotomy and remove disc material as needed, including cartilaginous endplates, using disc preparation instruments such as curettes, shavers, rasps, and/or other appropriate discectomy tools.

Decompress neural anatomy as required. Posterior stabilization should always be utilized at the appropriate level(s), before or after implant placement, as preferred by the surgeon.

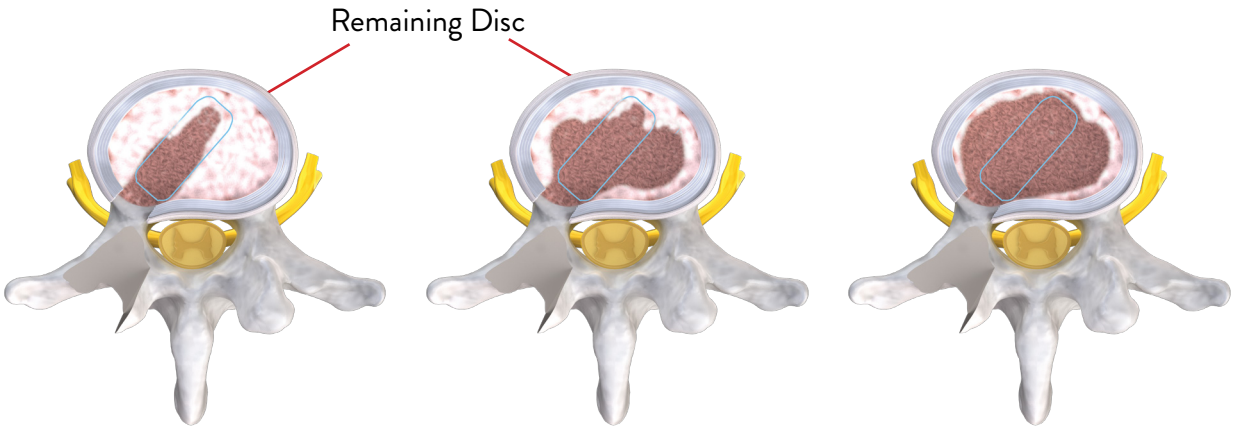
Following decompression, continue to perform a sufficient discectomy at the operative level(s) if necessary.

BIDIRECTIONAL DISC PREPARATION

The FlareHawk7 Implant requires disc prep and distraction strategies that accommodate a bi-planar implant. The FlareHawk7 Shell must have medial-lateral clearance to allow for expansion to 7 to 11mm width, especially at the distal tip of where the Implant will be placed. A channel discectomy is inadequate to allow for the large footprint the FlareHawk7 Implant provides. Leaving disc material in the path of expansion can prohibit deployment. When possible, a four -quadrant discectomy is encouraged to allow for width expansion and to take advantage of the flow-through of graft during post-packing. However, it is essential to remove at least enough disc material for the Implant to expand to 11mm in width.



Optimal Disc Prep



Inadequate Disc Prep

Inadequate Disc Prep

Adequate Disc Prep

Caution: Due to the width expansion capabilities of the FlareHawk7 Implant, adequate discectomy of the affected disc is necessary to place and expand the FlareHawk7 Implant. Failure to perform a sufficient discectomy may limit the Implant's ability to deploy properly. If a PLIF is being performed, it is important to make sure enough space is available to expand both Implants.

DISTRACTORS & SHAVERS

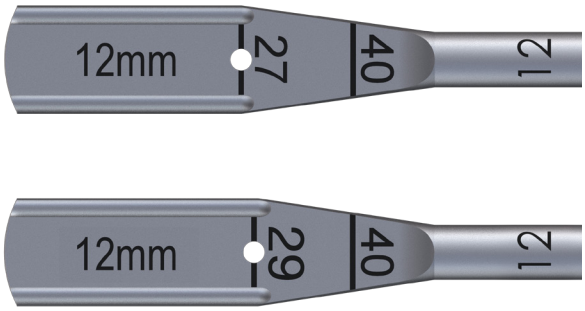
After the disc space is prepared for the 11mm-wide Implant, sequential dilation with Integrity Paddle Shaver(s) and/or Integrity Paddle Distractor(s) should take place until a Shaver or Distractor is found to be self-retaining and snug in the tallest portion of the disc space.

Begin by affixing the orange Hudson T-Handle to the desired Paddle Shaver or Paddle Distractor. While using the Paddle Shaver(s) or Paddle Distractor(s), confirm correct instrument placement and trajectory using fluoroscopy. The Shaver(s) have a through-hole that can be seen fluoroscopically to help assess depth within disc space. Compare the operative disc space(s) to healthy adjacent-level discs seen in preoperative radiographic images to assist in determining appropriate Implant height and lordosis.

It is strongly suggested in rigid spines that Distractors or Shavers are kept in place for adequate time to provide ligamentotaxis.

There are two variations of Integrity Shavers. One set of Shavers has a through-hole at 27mm and one set has a through-hole at 29mm. It is important to note which Shavers are in your set when determining depth through fluoroscopic reference of the through-hole. Integrity Paddle Distractors have a through hole at 27mm.

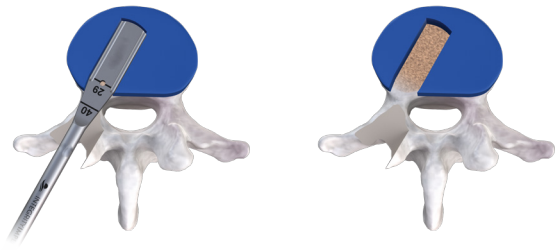
The disc space must always be distracted to at least the height of the selected Implant. There is no need to oversize the Implant and place the spine in a supraphysiological position. The Implant is deployed in an atraumatic fashion with a 11mm footprint designed to reduce settling.



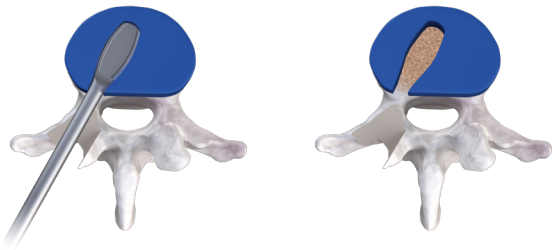
Caution: **It is advisable that the surgeon not deliberately select an Implant that is oversized relative to the disc space. If an Implant height is larger than appropriate for the disc space is used, increased resistance may be encountered when expanding and locking the implant.**

Note: **Use of the Integrity Paddle Distractor or Paddle Shaver(s) is highly recommended. Failure to use these instruments may result in increased resistance when deploying the Implant.**

Integrity Paddle Shavers and Distractors were designed to account for a bi-directionally expanding Implant and should be the only shavers or distractors used in the procedure. Most shavers and distractors create a football shape when rotated in the disc space.



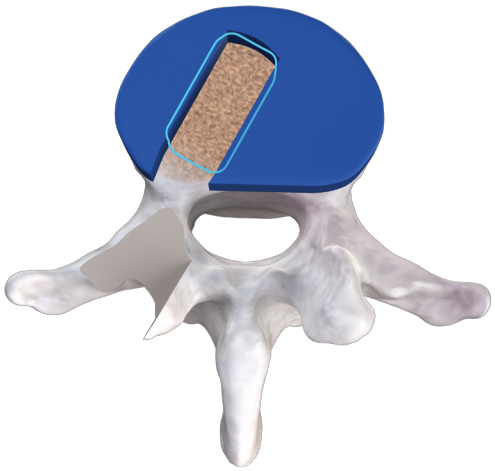
Integrity Shaver



"Football" Shaped Shaver

Integrity Shavers are designed to create a rectangular clearance in the space to allow room for the nose of the Implant to expand in width and height. Utilizing a football shaped shaver may not provide enough clearance for an Implant to expand bi-directionally.

Clear Expansion



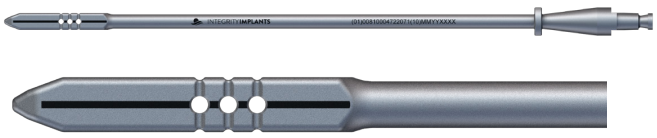
Impinged Expansion

SHORT & TALL OBTURATOR IMPACTORS

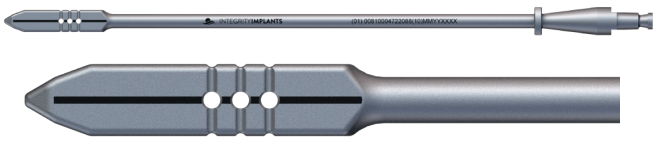
The Short and Tall Obturator Impactors have a through-holes at 26, 30, and 34mm and can be seen fluoroscopically to help assess depth within the disc space.

Affix an orange Hudson T-Handle to the selected Impactor, and insert the Impactor into the disc space with the hole running parallel to the endplates. The Short Obturator Impactor can be used for verification of an adequate working channel for insertion of a Short Shell. The Tall Obturator Impactor can be used for verification of an adequate working channel for insertion of a Tall Shell.

The Impactor can be utilized to determine if additional distraction or prep work may be required for Implant entry into the disc space. While using the selected Impactor, confirm correct instrument placement and trajectory using fluoroscopy.

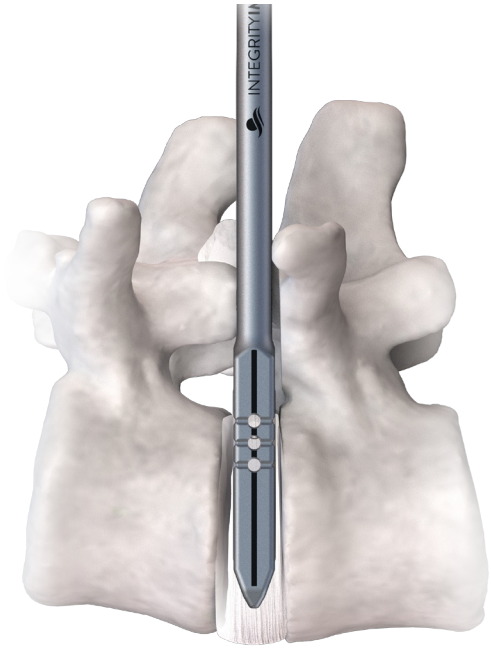


Short Obturator Impactor (ASY-00153)



Tall Obturator Impactor (ASY-00154)

Axial View



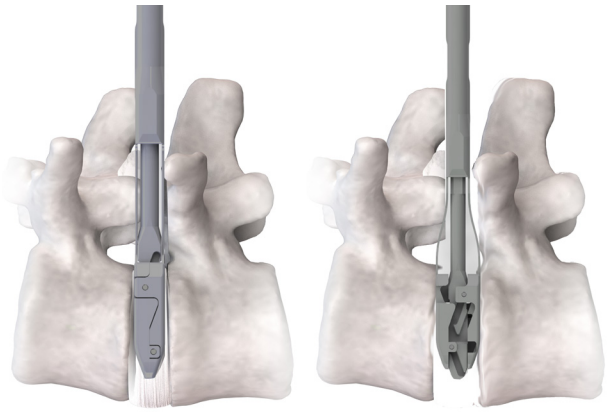
Lateral View

EXPANDABLE TRIAL

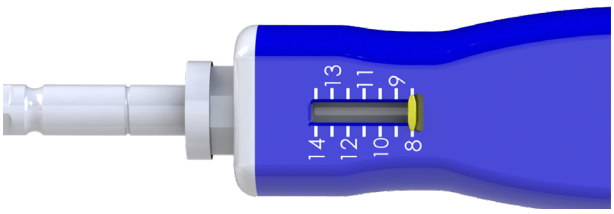
The 0° Expandable Trial is designed to provide incremental distraction of the disc space and trialling without passing the Paddle Distractors by the neural anatomy. The footprint of the Trial is similar to the unexpanded profile of the Implants at 7mm wide and features a height of 8mm. Begin by connecting the Tear Drop Handle to the proximal portion of the Expandable Trial. Insert the Expandable Trial into the disc space. Once the location has been confirmed via fluoroscopy, using only two fingers, rotate the Tear Drop Handle clockwise until slight resistance is felt (approximately "finger tight"), and stop to verify size. Suggested Implant height will be displayed on the Height Indicator located near the handle portion of the instrument.

The 0° Trial provides an incremental distraction and trialling from 8mm to 14mm.

Axial View



Lateral View - Closed *Lateral View - Expanded*

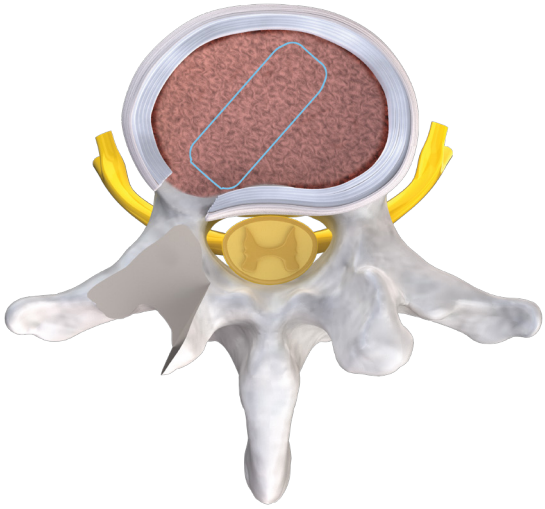


Height Indicator

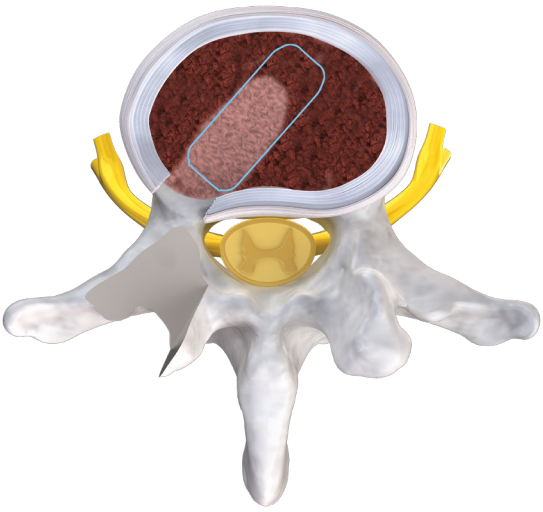
Caution: **Only expand Trial Instrument until resistance is encountered. Over-distraction could cause vertebral body damage and/or instrument damage.**

PRE-PACKING GRAFT

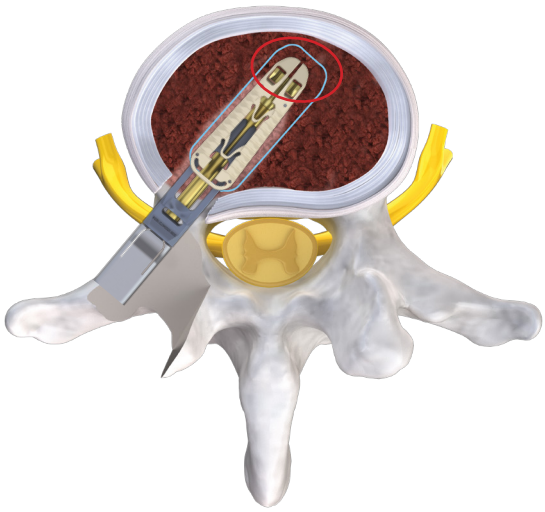
Graft placement is critical to obtaining fusion. Many surgeons may pre-pack graft in the disc space before inserting an Implant. FlareHawk7 is designed to be post packed. Large axial and lateral windows in the Implant allow for the flow of graft from endplate-to-endplate and also throughout the lateral windows into the cleared-out disc space. Since FlareHawk7 expands both in height and in width, it is important to leave space around the FlareHawk7 Implant to expand from 7mm to 11mm in width.



Optimal: No Pre-Packed Graft



Pre-Packed Graft



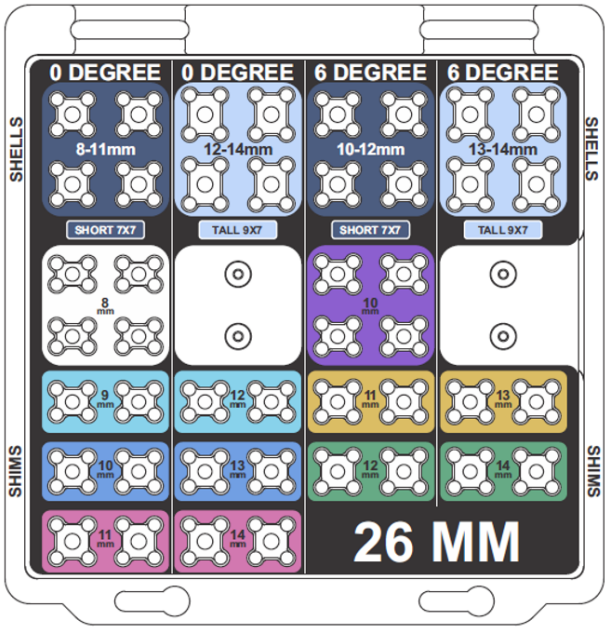
Impinged Expansion

Caution: **It is highly advisable to not pre-pack graft. Pre-packed graft can impinge expansion of the Implant. If graft is placed prior to Implant insertion, it is recommended the surgeon utilize either an Impactor, Distractor, or Shaver to clear an 11mm-wide pathway for the Implant.**

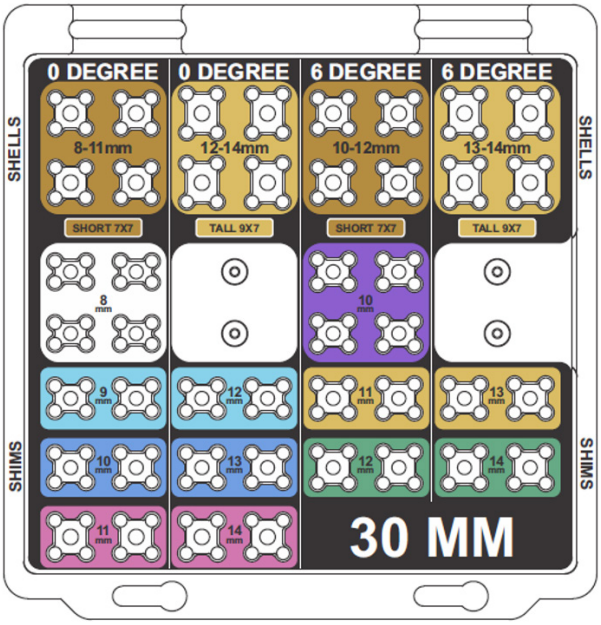
IMPLANT **SELECTION**

Once the surgeon determines the desired Implant length, height, and lordosis for the disc space, the appropriate Shim and Shell combination is selected from the Implant Caddy. The specific selection of the Shim and Shell will achieve the desired height and lordosis upon deployment in the disc space. A deployed FlareHawk7 reaches the desired height and lordosis upon lock-out and cannot be stopped short or increased to greater heights than what was selected. If the surgeon desires a different height or lordosis, another Shim and Shell combination must be selected.

The Implant Caddy is designed to guide the scrub tech in selecting the appropriate Implant. There are two caddies, a 26mm Caddy and a 30mm Caddy. Implants from different caddies should never be combined. All Shims and Shells of the same color within the Caddy are the same. Each Caddy has four columns or "lanes" designated by degrees of lordosis and height range. The scrub tech should stay within the same lane when selecting the Shell and Shim. All Shims and Shells are color coded, so if there are Implants missing from a needed section, simply select the same color Shim or Shell to the direct left or right of the color coded empty space.



26mm Caddy



30mm Caddy

Example: **The surgeon requests a 30mm Length, 12mm Height, 6 Degree Implant.**

STEP 1

Choose the Implant Caddy that contains the desired Implant length, as indicated by its label plate. In this example, the 30mm Caddy is selected.

STEP 2

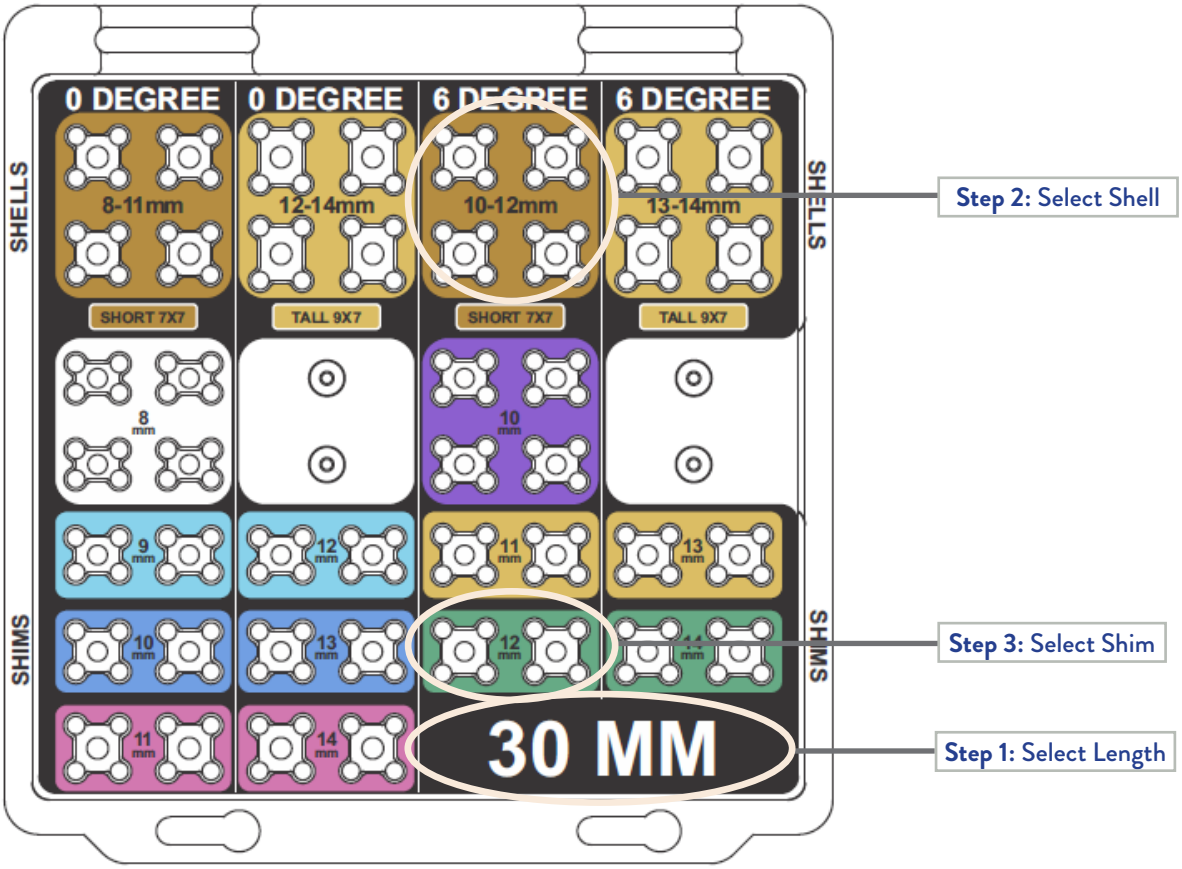
Go to the columns labeled 6 DEGREE and select the Shell located in the section where the height range is listed. In this example, the bronze Short Shell is selected since it is found in the bronze 10-12mm section within the corresponding 6 DEGREE column. The color of the Shell can be seen by looking at the Core.

STEP 3

Select the green 12mm Shim found directly below the selected Shell.

The combination of the 12mm Shim and the Shell found within the 6 DEGREE column will make a 12mm, 6 Degree Implant once fully expanded in the disc space.

Staying within the selected lane will ensure the right Implant combination is chosen.



INSERTER **LOADING**

Once the desired Shell and Shim have been selected, perform the following steps:

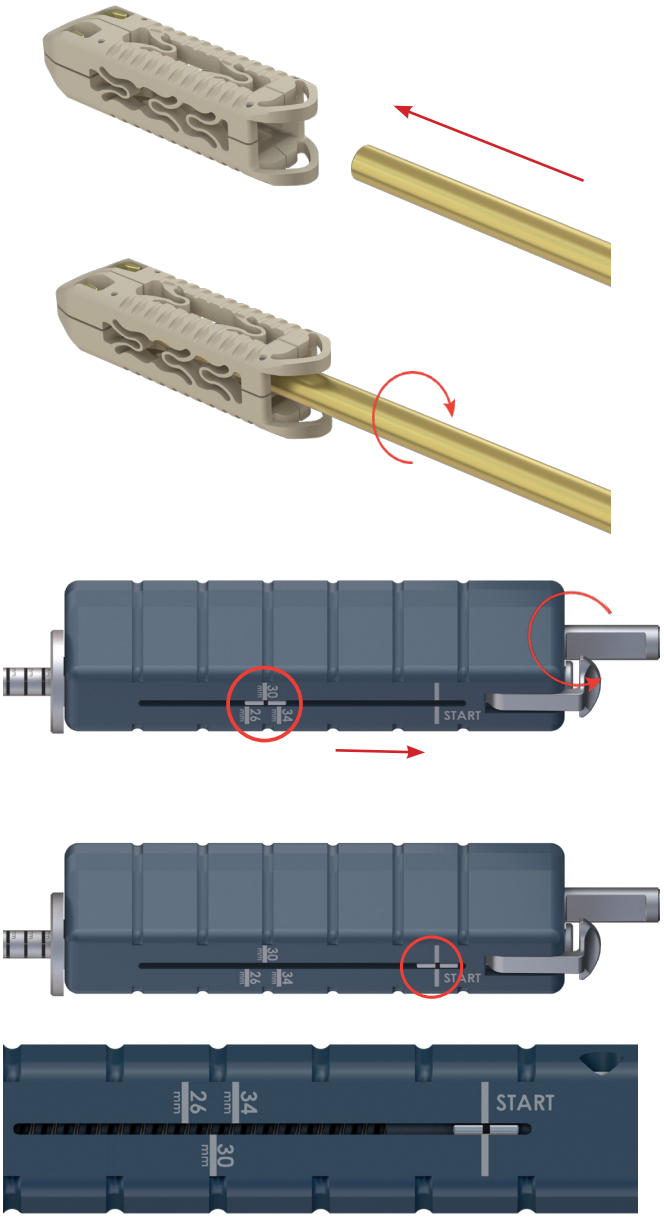
STEP 1

With the Shell still in the Caddy, attach the gold FlareHawk7 Guide Pin to the desired Shell. To do this, screw the female thread on the Guide Pin clockwise onto the male thread inside the Shell until it is completely tightened and a hard stop is felt.

STEP 2

Before loading the Shim or Shell onto the Inserter, rotate the drive shaft of the Inserter counterclockwise until the indicator tab (indicated by the red circle to the right) is fully bottomed out at the back end of the Inserter in the "Start" position. This will ensure the Guide Pin is properly engaged with the Inserter.

The Inserter has 26mm, 30mm, and 34mm laser markings along the travel of the indicator. When the indicator reaches or has traveled past the designated marking of the selected Implant length during deployment, the Implant should become locked. This indicator does not replace fluoroscopic visualization for lock confirmation.



Note: The Inserter must be properly maintained and serviced to ensure optimal performance. Surgical instrument lubricant should be regularly applied to its internal mechanisms.

Note: Guide Pins are single-use only and are not to be re-used. FlareHawk7 Guide Pins are colored gold and are not interchangeable with FlareHawk9. Similarly, the FlareHawk7 Inserter is blue and is not interchangeable with FlareHawk9.

Note: Over-tightening the Guide Pin onto the Core can cause the Core to rotate out of place within the Shell. If this occurs, another Shell must be selected.

STEP 3

With the Shim still in the Caddy, affix the desired Shim to the prongs at the tip of the Inserter and remove the Shim from the Caddy.

STEP 4

Insert the proximal end of the Guide Pin through the cannulated nose of the Shim into the Inserter's central lumen until a noticeable "click" is heard. This click confirms the Guide Pin is locked within the Inserter.

STEP 5

Tug firmly on the Shell to confirm it is locked into place. If it isn't, repeats Step 2 & 4.

STEP 6

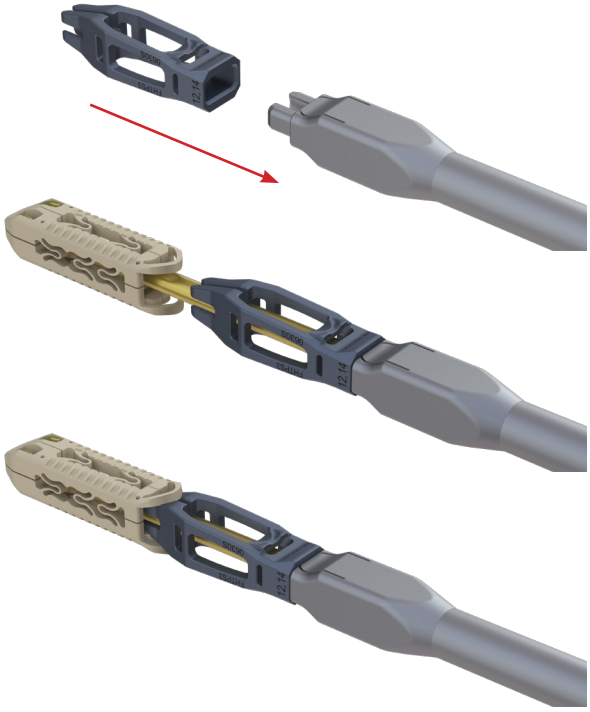
Ensure the orientation of the Shell relative to the Shim is correct. In the correct orientation, the Shell's backstraps will point toward the split in the Shim and the flat section of the Inserter's tip, as shown below.

Rotation Misaligned

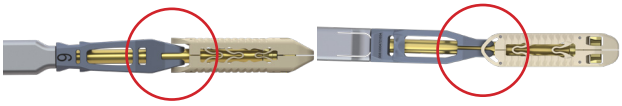
Correct Alignment

STEP 7

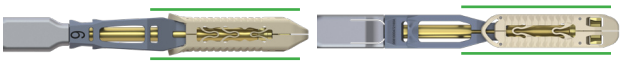
Advance the Shim slightly into the Shell. The backstrap may slightly flare up from the nose of the Shim. This will help remove the toggle of the Shell in relation to the Shim, limit Shell rotation during insertion, and ensure the Shim and Shell remain properly aligned. See illustrations to the right.



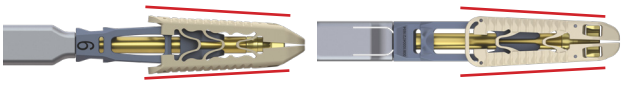
Audible "click" is heard when Guide Pin is locked into the Inserter.



Too Little Engagement



Good Engagement



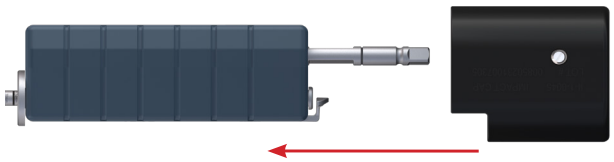
Too Much Engagement

IMPLANT INSERTION & **DEPLOYMENT**

Prior to impaction of the Shell into the disc space, perform the following steps:

STEP 1

If desired, the surgeon may pre-pack the disc space with autograft and/or allograft. If this is done, the surgeon must ensure sufficient space remains to allow for expansion of the FlareHawk7 Implant.



STEP 2

Slide the Impaction Cap over the Inserter's drive shaft until it clicks into place.

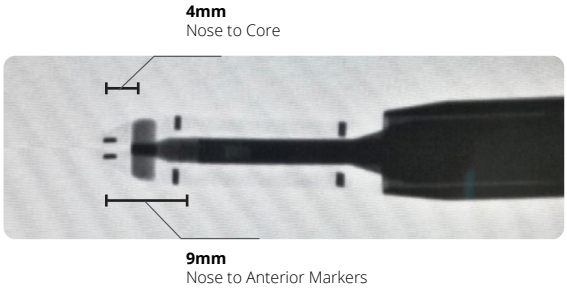
STEP 3

Position the Inserter at the desired trajectory relative to the disc space. Verify that the Inserter and Implant are properly aligned, with the Shell's teeth facing the endplates and the body of the Inserter parallel to the endplates.

Note: Pre-packing graft without ensuring proper clearance for the Implant to deploy to 11mm wide may cause increased resistance when deploying the Implant.

STEP 4

Advance the Shell into the disc space utilizing the palm of the hand to impact on the back of the Impact Cap. Use fluoroscopic guidance to assist with placement and keep in mind the PEEK nose of the Implant is 4mm in front of the titanium Core when viewing the images. If the Shell begins to rotate relative to the Shim, instead of trying to control the Shell with the Inserter, orientate the Inserter and Shim to follow the Shell into the disc space. This will help the Shim and Shell stay in proper orientation for deployment.



Lateral View

Caution: Impaction with a mallet may be required to fully advance the Shell into the disc space. Once the Shell is fully impacted, do not attempt to manipulate its position, as this may damage the Shell's interface with the Guide Pin.

Note: During insertion and deployment, the surgeon should be mindful of the Inserter's orientation relative to the orientation of the Implant. Maintaining a consistent orientation between the Implant and the Inserter will help guide the Implant in the desired trajectory.

STEP 5

Select the T-Handle and attach it to the Inserter's drive shaft. Rotate the handle counterclockwise and press down until it is fully engaged (as indicated by alignment with the recessed line on the drive shaft). An audible click alone may not indicate correct T-Handle engagement.

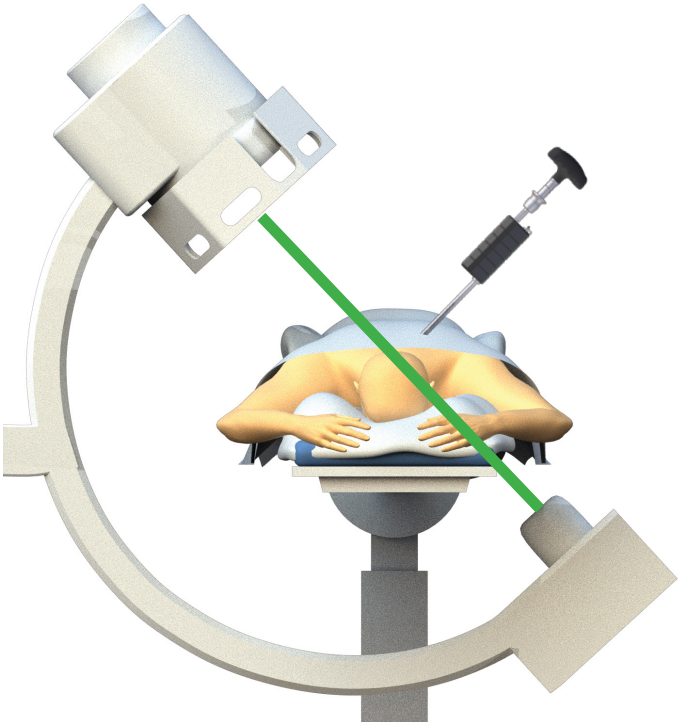
Always ensure the T-Handle is fully engaged with the Inserter before attempting to deploy the Implant. When the T-Handle is correctly seated, the recessed line on the Inserter's drive shaft will line up with the distal end of the T-Handle.

Caution: **Do not impact on the Fixed T-Handle, as this may damage the instrument. If mallet use is necessary, always affix the Impaction Cap to the Inserter.**

STEP 6

Once the T-Handle is engaged, place the C-arm in the contralateral oblique position for deployment and locking confirmation. With a standard C-arm, position the flat face of the image intensifier parallel to the Inserter (see image below). This will approximate the correct angle for a lateral image of the Implant.

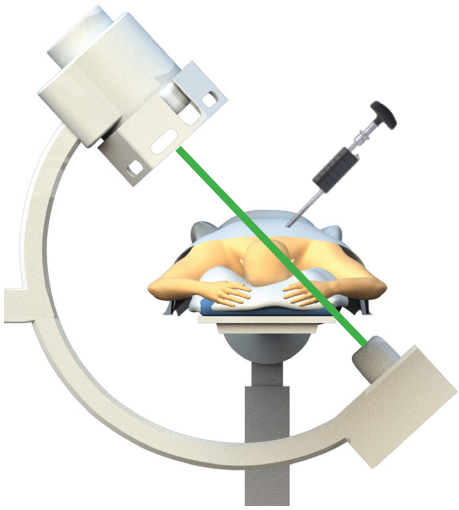
Setting up the C-arm in the contralateral oblique orientation will allow the surgeon to view the orientation of the Shim relative to the Shell during deployment as well as confirm the Implant is locked when fully deployed.



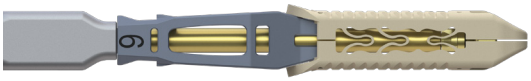
Note: In order to obtain a direct lateral image of the Implant during a TLIF, the C-arm must be placed on the opposite side from which the surgeon is performing the surgery.

STEP 6 (CONT.)

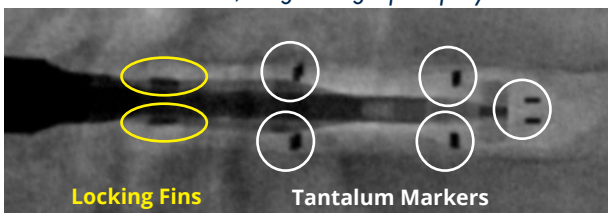
The Shim's locking fins should be dark and distinct compared to the rest of the Shim. The Shell's eight tantalum markers should be relatively aligned with one another so it appears as though there are four markers. Maintaining this orientation during deployment will help ensure a proper deployment and allow for lock confirmation via fluoroscopy.



Proper Shim/Shell orientation

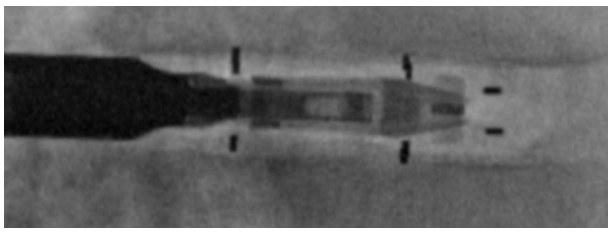


Initial Insertion, Beginning of Deployment

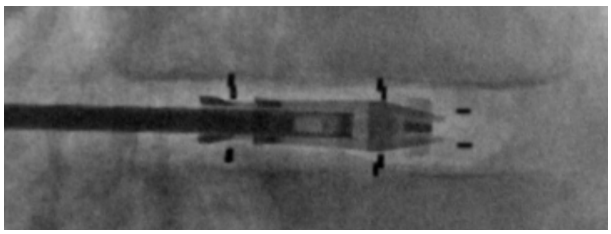


50% Deployment

100% Deployment and Locked

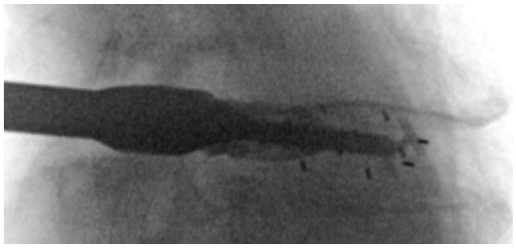


Locked with Guide Pin, Inserter Removed



When the C-arm is not in the contralateral oblique position (image to right), the fins on the Shim and the markers in the Shell are not aligned. This makes it difficult to ensure the Shim and Shell are aligned properly to help ensure deployment will occur.

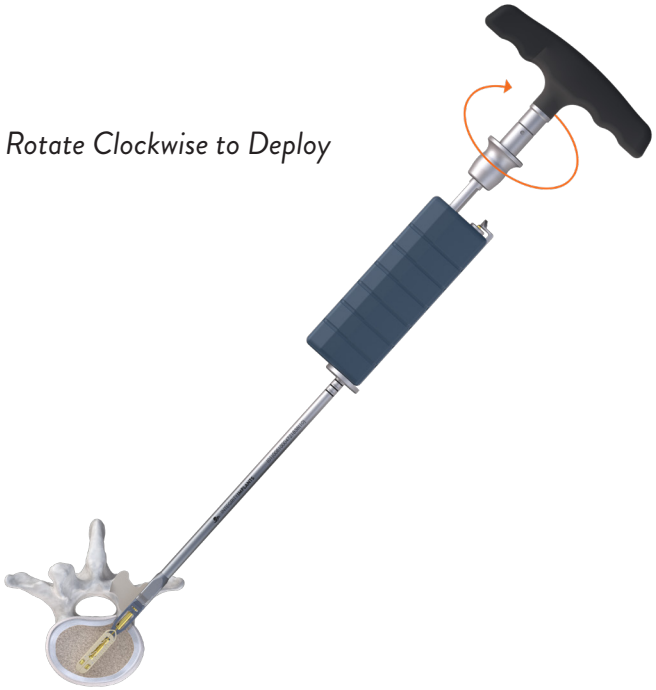
Initial Insertion, C-arm in True Lateral to Spine



STEP 7

To expand the Implant, advance the Shim into the Shell by rotating the T-Handle clockwise until the audible locking click is heard. Once the audible click is heard, the surgeon should use two fingers to rotate the handle gradually until resistance to turning is felt. Confirm Implant placement and trajectory via fluoroscopy during expansion. Once the Shim is locked into the Shell, the Fixed T-Handle should not be rotated further and the lock should be confirmed via fluoroscopy as shown on the next page. Failure to limit the advancement of the Inserter in this manner may result in damage to the instrument or Implant. The surgeon should be mindful of the Inserter's orientation while deploying the Implant to avoid unintentionally rotating the Shim relative to the Shell.

Rotate Clockwise to Deploy



Not Deployed *Partially Deployed* *Fully Deployed*

Caution: **Once the Shim is locked into the Shell and resistance to turning further is encountered, the Fixed T-Handle should not be rotated further. Failure to limit the advancement of the Inserter in this manner may result in damage to the instrument or Implant, including Guide Pin and core disassociation.**

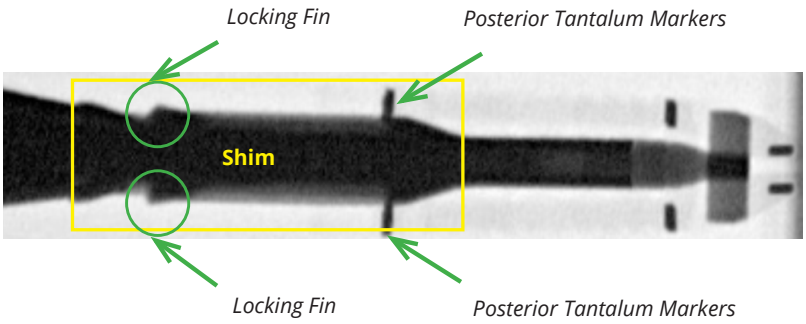
Caution: **Attempting to reposition the Implant following deployment is not recommended.**

Caution: **An unlocked Implant or Implant without a Shim should never be left in a patient.**

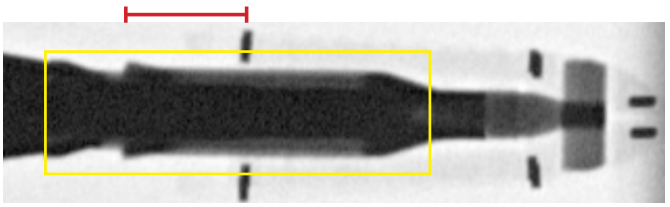
LOCK **VERIFICATION**

As the Shim is inserted into the Shell, a tactile and audible click may be heard when the lock engages. This indicates that the Implant is fully deployed. Nevertheless, lock engagement should always be confirmed using fluoroscopy.

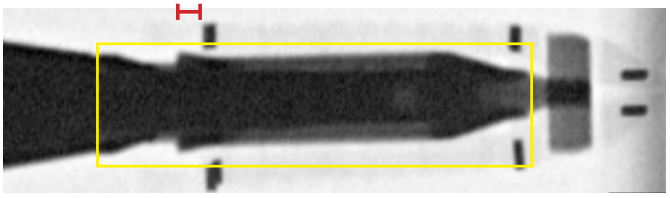
The series of images below show the progression of the Shim advancing into the Shell during deployment under fluoroscopic view. In the images below, the Lock Confirmation Window is blocked by the Inserter tip and Guide Pin. It is important to pay attention to where the Locking Fins are in relation to the Posterior Tantalum Markers. When the Implant is fully deployed and locked, the Locking Fins will be anterior to the Posterior Tantalum Markers.



Not Locked

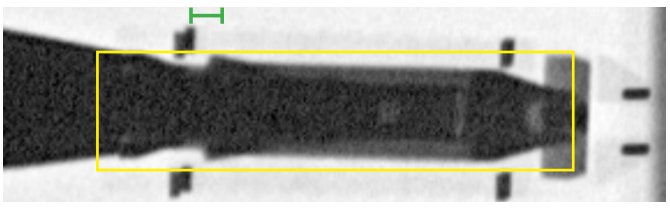


Not Locked

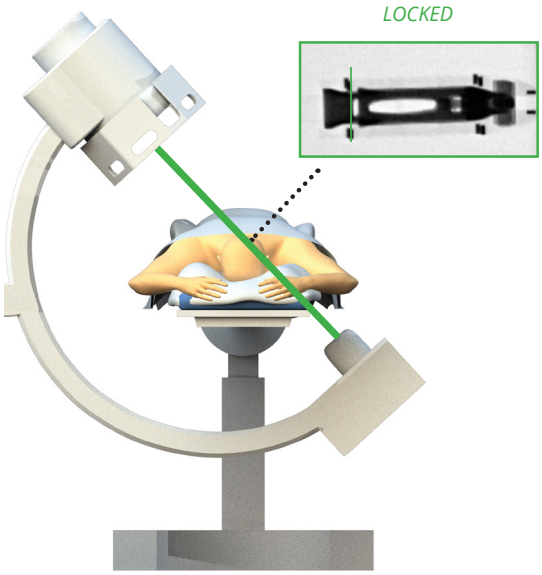


Locked

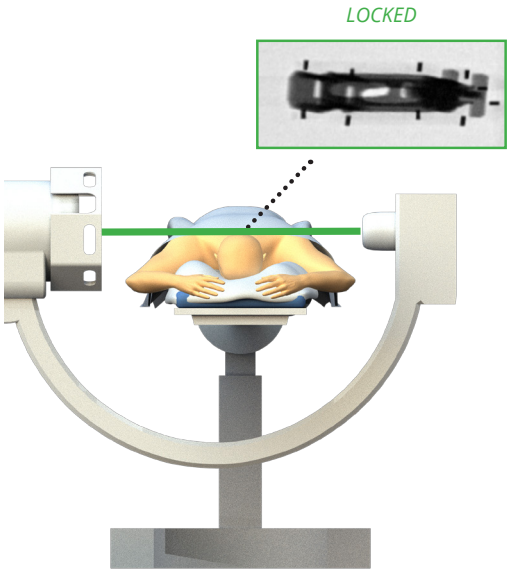
Locking fins anterior to the posterior tantalum markers.



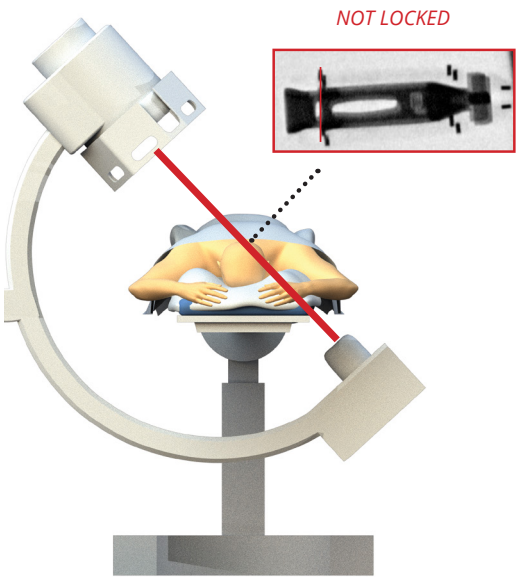
The images below show a deployed Implant after the Inserter and Guide Pin have been removed. A Lock Confirmation Window can be seen at the posterior portion of the Shim. When fluroscopically assessing the lock in this view, note that the posterior tantalum markers are posterior to the Lock Confirmation Window. These images illustrate the importance of taking a contralateral oblique fluoroscopic image of the Implant to confirm it is locked. As seen in the lateral image, it is not always possible to visually confirm the Implant is locked until a contralateral oblique image of the Implant is taken.

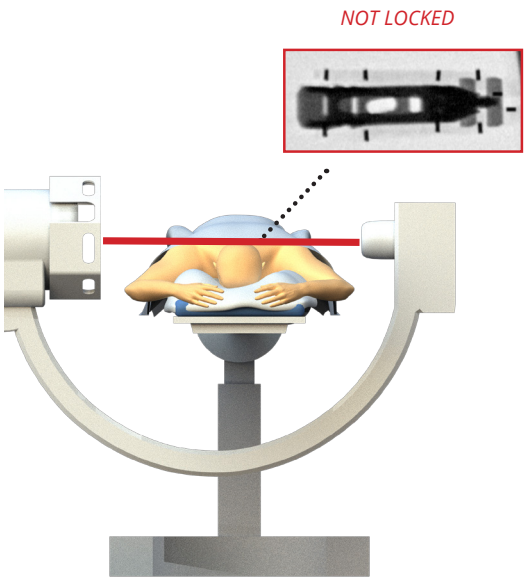


Contralateral Oblique



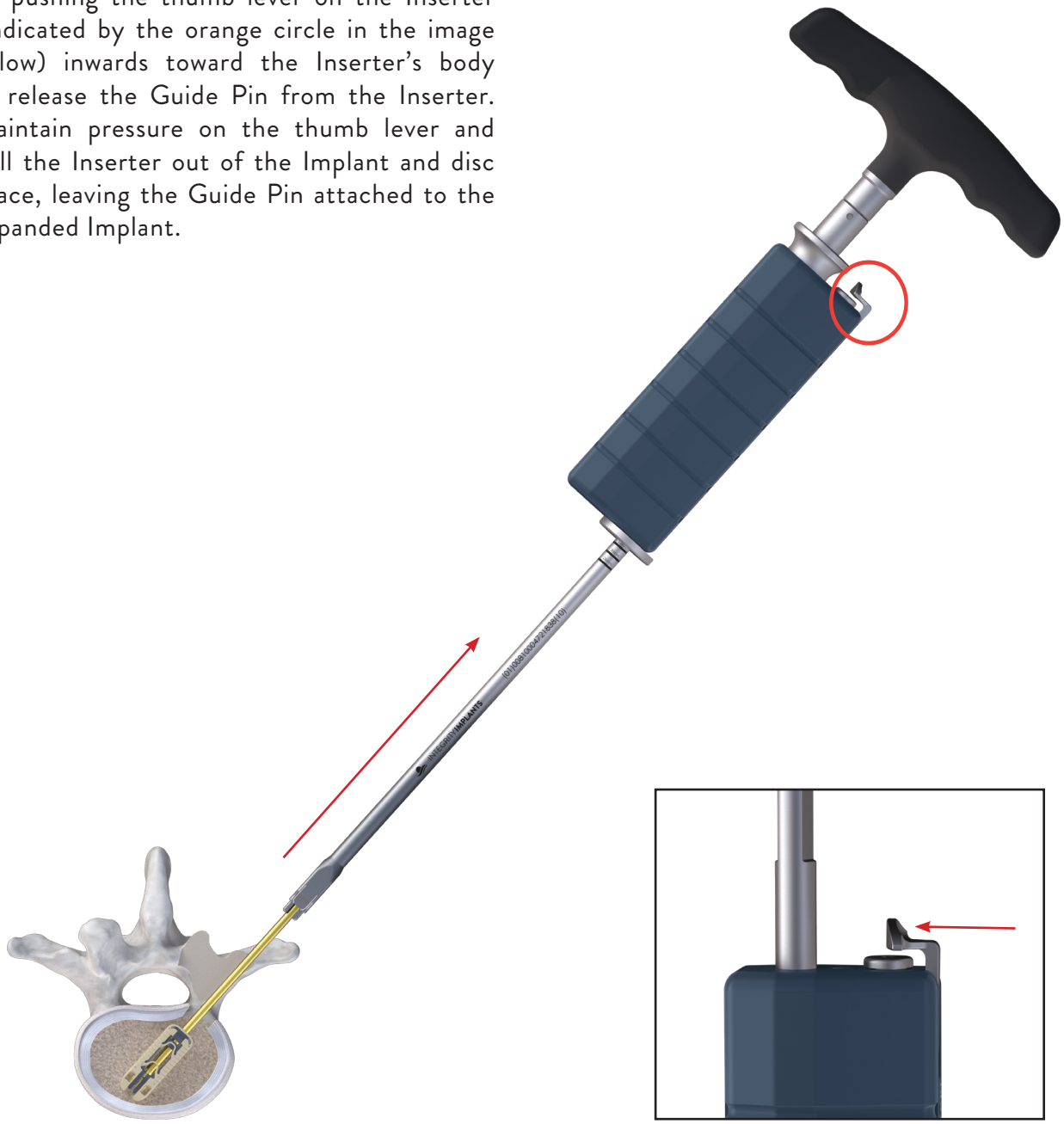
Lateral





INSERTER **REMOVAL**

After Implant lock confirmation, rotate the T-Handle counterclockwise one full turn to release the tension on the Guide Pin. Disconnect the Inserter from the Guide Pin by pushing the thumb lever on the Inserter (indicated by the orange circle in the image below) inwards toward the Inserter's body to release the Guide Pin from the Inserter. Maintain pressure on the thumb lever and pull the Inserter out of the Implant and disc space, leaving the Guide Pin attached to the expanded Implant.



Depress Guide Pin release button to remove Inserter

LOCK **GAUGE**

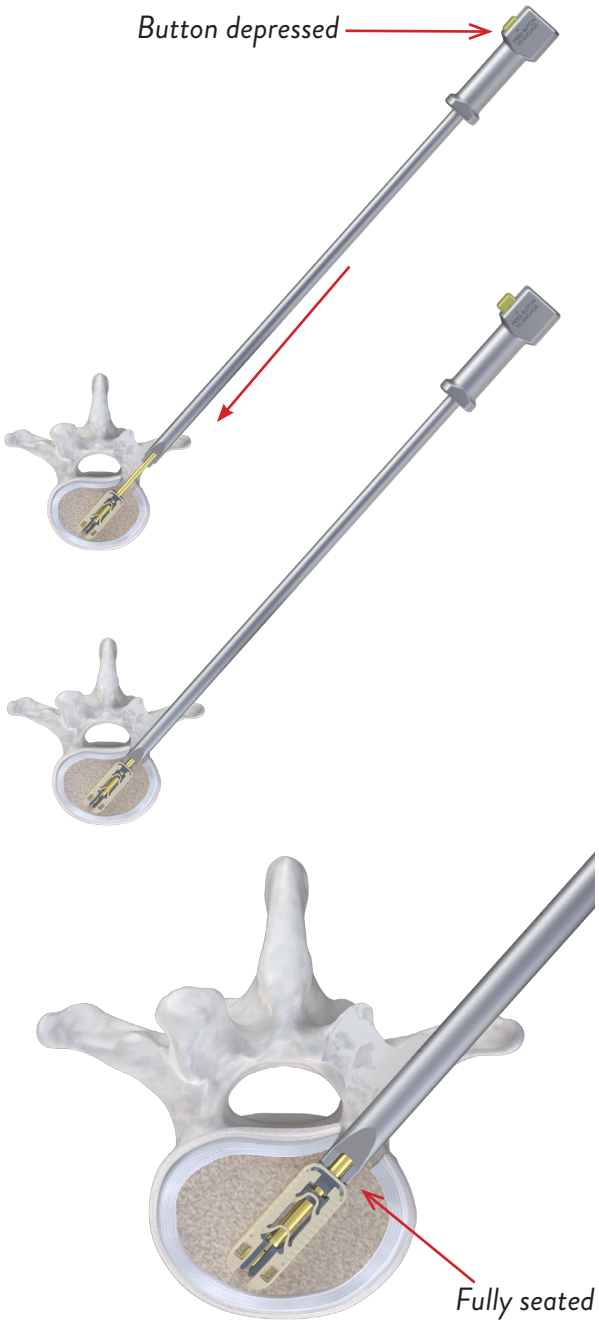
After the Inserter has been removed, the 26mm or 30mm Lock Gauge can be utilized as additional lock confirmation. This instrument does not replace fluoroscopic visualization as the primary form of lock confirmation.

Confirm the guide pin is fully threaded to the core by turning the guide pin clockwise. If it is fully seated no turning will occur, but if it turns, continue turning until a stop is felt. The Guide Pin Wrench can be utilized to ensure the Guide Pin is threaded to the core.

Select the Lock Gauge that matches the Implant length that was deployed. Fully depress the button on the proximal end while sliding the gauge over the guide pin into the back of the Shim of the deployed Implant. The flats of the tip and handle should align with the flats of the end plate and the orientation of the deployed Implant.

The Lock Gauge should be fully seated into the back of the Shim. This may be seen visually or confirmed fluoroscopically. If the Lock Gauge is fully seated, the surgeon should be able to see the tip of the gold Guide Pin in the guide pin hole in the back of the handle.

If the surgeon cannot see the tip of the guide pin in the hole, the Lock Gauge is not fully seated.



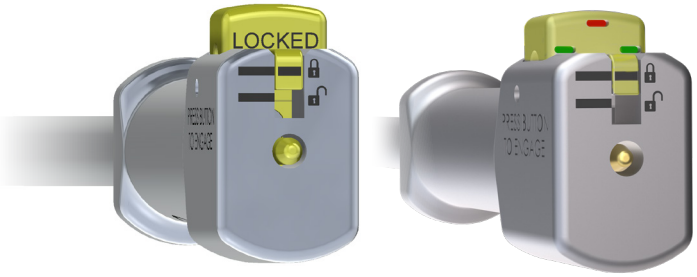
Once fully seated, release the button on the Lock Gauge. If the Implant is locked, the laser mark on the button should align with the lock symbol. Depending on which version of the Lock Gauge is in the set, green marks should appear on button when it is locked, or the word “LOCKED” will be visible on the button when it is locked. If the Implant is not locked, the laser mark on the button should align with the unlocked symbol.

Once lock is confirmed, fully depress the button and slide the Lock Gauge off the Guide Pin.

If the Implant is not locked, remove the Lock Gauge by fully depressing the button and sliding the Lock Gauge off the Guide Pin. Re-attach the Inserter to the Implant and Guide Pin to finish the deployment. If the Implant still does not lock, utilize the removal tools to remove the Implant. After removal another Implant can be placed.

NEWER VERSION

Implant Unlocked



NEWER VERSION

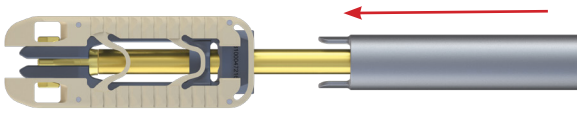
Implant Locked

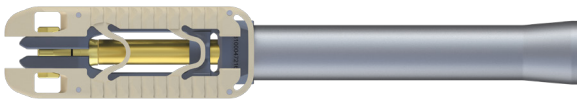
BONE FUNNEL **PREPARATION**

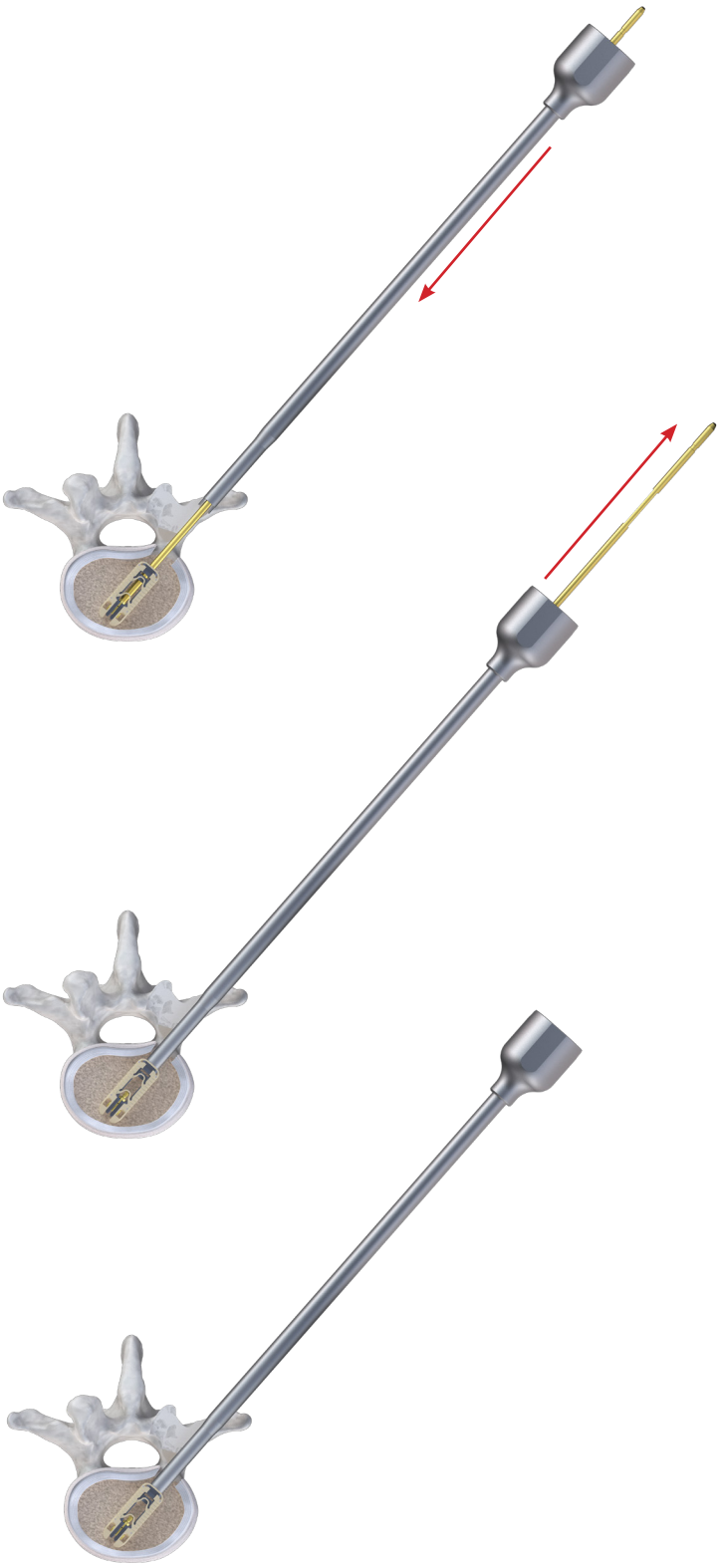
To place the Bone Funnel, slide it over the Guide Pin until the tip of the Bone Funnel engages with the posterior window of the Shim. Ensure that the two prongs at the Bone Funnel's tip are correctly seated in the posterior aperture of the Implant. Keep the Bone Funnel engaged throughout the graft delivery process by maintaining consistent downward pressure.

Unscrew and remove the Guide Pin by rotating it counterclockwise. This may be done using the Guide Pin Wrench or the surgeon's fingers. Once the Guide Pin has been removed, fill the Bone Funnel with autograft and/or allograft. To reduce the chance of clogging, ensure the bone graft is adequately morselized. All particles should be 3mm in size or smaller.

Alternately, the Bone Funnel may be preloaded and placed freehand if the Guide Pin is removed beforehand. Please note that Bone Funnel should be loaded as close to the time of usage as possible to avoid solidification or drying of the bone graft within it.



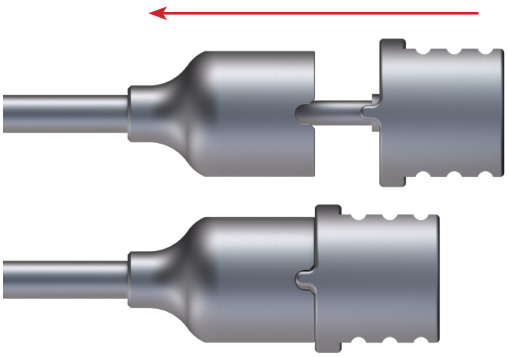




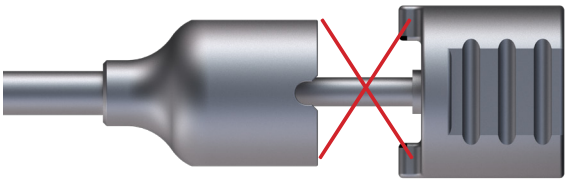
BONE GRAFT **DELIVERY**

Using the Bone Tamp, push the bone graft through the Bone Funnel into the deployed FlareHawk7 Implant while maintaining consistent downward pressure on the Bone Funnel. Continue to advance the Tamp until all graft in the Bone Funnel is delivered. If the Tamp will not advance, discontinue impaction and remove the Tamp. It is not recommended to use a mallet on the Tamp.

Repeat the Bone Funnel Preparation and Bone Graft Delivery steps as many times as needed, until the Implant is sufficiently packed with allograft and/or autograft.



Correct Alignment



Incorrect Alignment

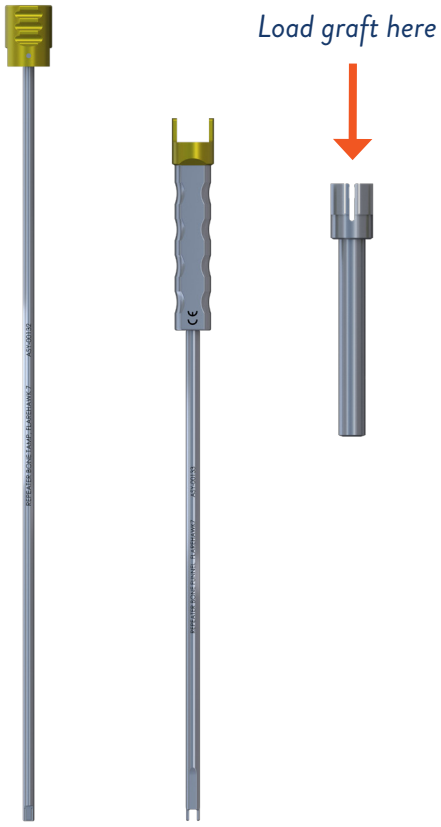
GRAFT DELIVERY PROCESS

Images for illustration purposes only.

Caution: **If the Bone Tamp will not advance through the Bone Funnel, do not attempt to impact it with a mallet, as this may damage the Implant.**

BONE GRAFT DELIVERY **WITH REPEATERS**

The Repeater Bone Funnel system consists of three components: Bone Funnel, Bone Funnel Crucible, and Bone Tamp.



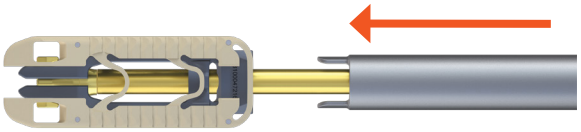
STEP 1

On the back table, load the desired number of Crucibles with bone graft, just as you would with a standard bone funnel. Each Crucible holds approximately 2cc of bone graft. Ensure the autograft is appropriately morselized (all particles should be less than 3mm in size) to reduce the chance of clogging. Please note that the Crucibles should be pre-loaded as close to the time of usage as practicable to avoid binding or drying of the bone graft inside the Crucible.

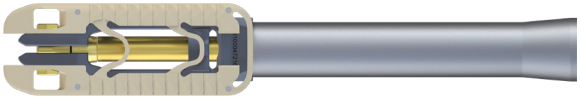
Repeat the Bone Funnel preparation and graft delivery steps as many times as needed, until the Implant is sufficiently packed with allograft and/or autograft.

STEP 2

Dock the tip of the Bone Funnel in situ into the graft window of the deployed Implant. Ensure that the two prongs at the Bone Funnel's tip are correctly seated in the posterior aperture of the Implant.



If desired, the Bone Funnel can be passed over the Guide Pin while the Guide Pin is still attached to the deployed Implant. If this is done, the Guide Pin must be removed before the Crucible is used. Alternatively, the Bone Funnel can be placed freehand following removal of the Guide Pin.



STEP 3

Insert one pre-loaded Crucible into the top section of the Bone Funnel. Ensure that the Crucible is properly seated in the Funnel. When properly placed, the Crucible will be completely flush with the top of the Funnel.

STEP 4

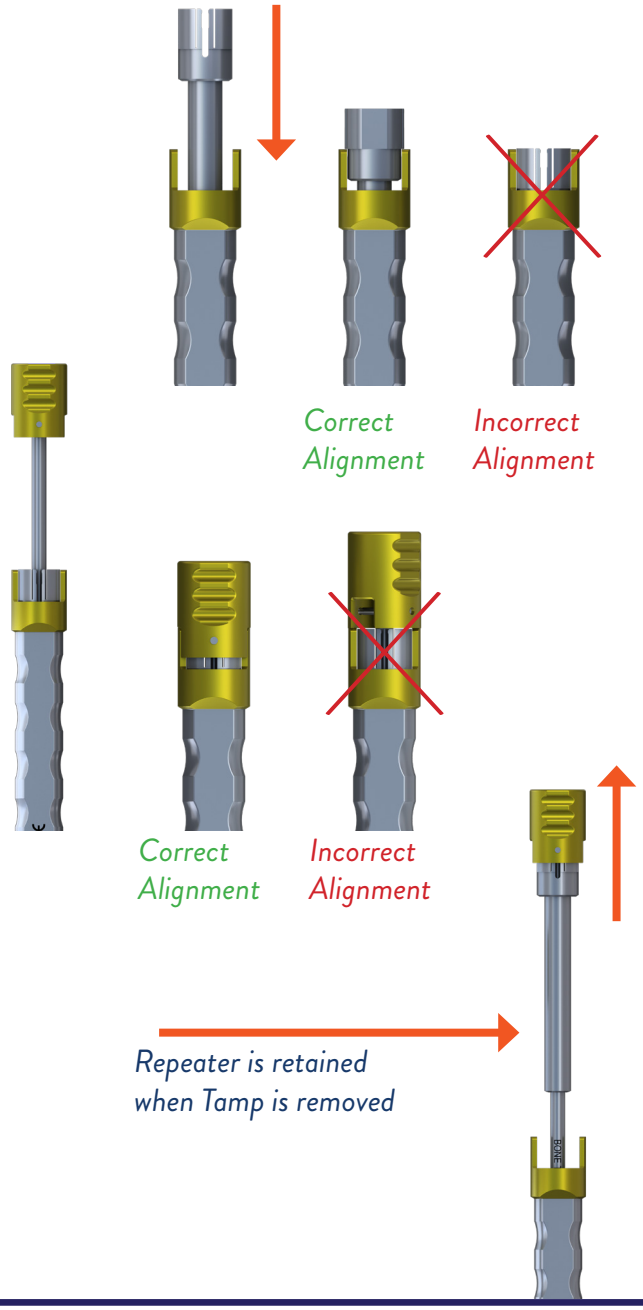
Using the Bone Tamp, push the bone graft in the Repeater through the Funnel and into the deployed Implant. Continue to advance the Tamp until it clicks into the top of the Repeater. To do this, the Tamp and Repeater must be properly aligned.

STEP 5

Once the Tamp is completely advanced and the Repeater is empty, remove the Tamp from the Funnel. The Tamp will automatically retain and remove the Repeater. Once the Tamp is completely removed, detach the empty Repeater from the Tamp.

STEP 6

Repeat steps three through five as many times as needed until the Implant is sufficiently packed with bone graft. Empty Repeaters may be reloaded and used as needed. Once autograft delivery is complete, remove the Bone Funnel and Bone Tamp.



Note: **The Repeater, Bone Funnel, and Bone Tamp are not disposable.**

Note: **The FlareHawk7 and Bone Tamp are not interchangeable with FlareHawk9 or TiHawk9.**

STEP 1

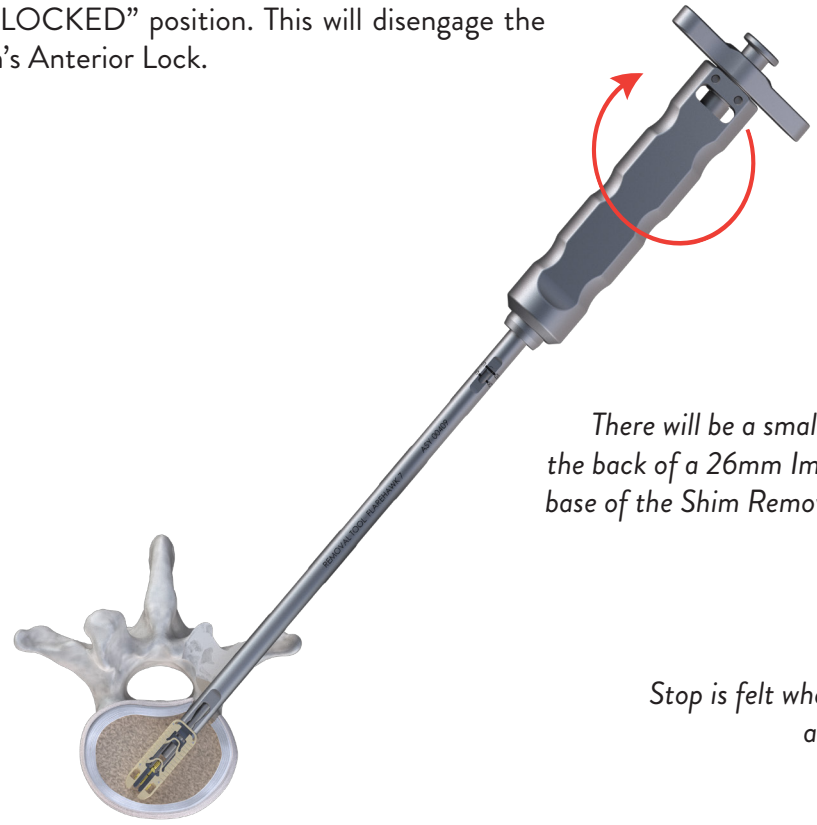
To use the Shim Removal Tool, rotate the proximal knob on the Shim Removal Tool counterclockwise until the lock indicator on its shaft is in the "LOCKED" position. Insert the instrument into the back of the Shim until its tip is completely within the Implant and a stop is felt. Using fluoroscopy, confirm that the tip of the instrument is completely seated within the Implant. There will be a small gap between the back of a 26mm Implant and the base of the Shim Removal Tool shaft.

Shim Locked Position

Shim Unlocked Position

STEP 2

While maintaining downward pressure on the Shim Removal Tool, rotate its proximal knob clockwise until the lock indicator reaches the "UNLOCKED" position. This will disengage the Shim's Anterior Lock.

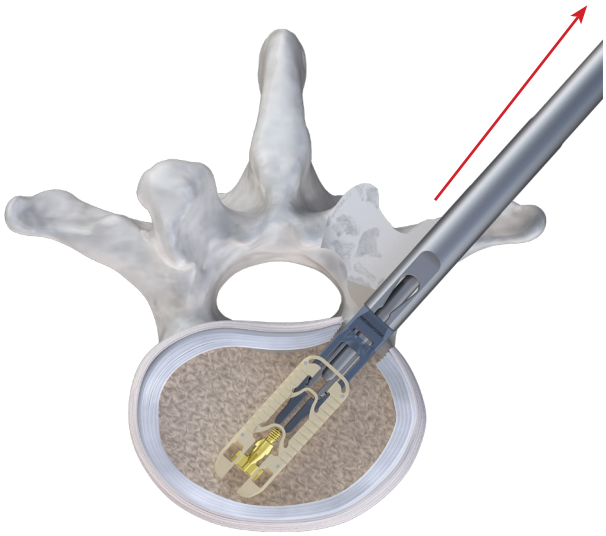


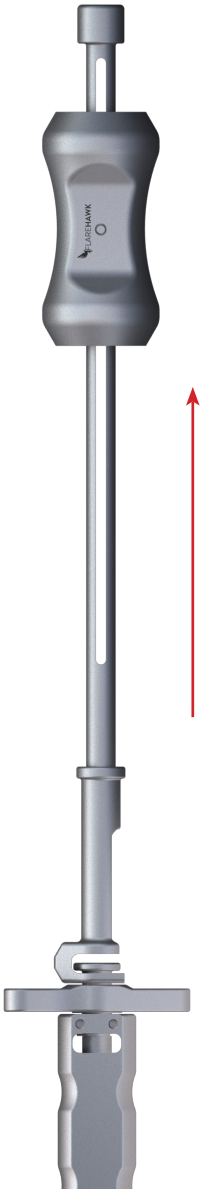
There will be a small gap between the back of a 26mm Implant and the base of the Shim Removal Tool shaft.

Stop is felt when instrument abuts the core.

STEP 3

Carefully pull upward to remove the Shim from the Shell. Monitor the Implant visually and/or fluoroscopically to verify the position of the Shim and Shell during removal. Alternately, the Slap Hammer may be affixed to the Shim Removal Tool and used to assist with Shim removal. This should overcome the Posterior Lock.





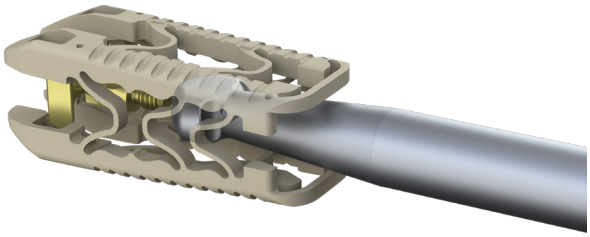
Caution: Never re-use a Shim, Shell, or Guide Pin.

Note: The interface between the Shim Removal Tool and Slap Hammer should be grasped firmly during use to ensure a consistent connection between the two instruments is maintained.

Note: Removal of the Shim from the Implant assembly for any reason requires removal of the Shell and replacement with a new Shell.

STEP 4

Once the Shim is removed, insert the Shell Retriever into the Shell until a hard stop is felt. The flats of the Shell Retriever tip should be parallel with the flats of the Shell and endplates. Rotate the instrument ninety degrees to grab the flexors of the Shell.

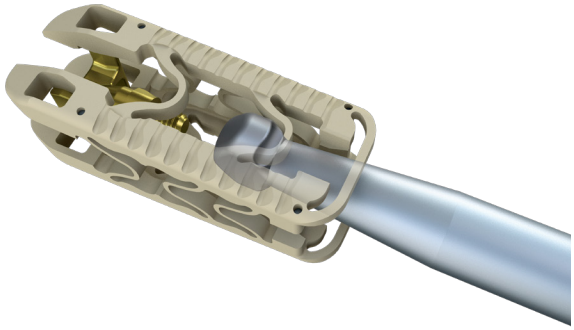


Shell Retriever fully seated in the Shell

STEP 5

Pull the Shell out of the disc space using the Shell Retriever. If desired, the Slap Hammer may be used. Monitor the Shell's progress visually to verify that removal is effective.

Ensure tip of Shell Retriever is parallel with the Shell and endplates



Rotate instrument 90^0 to grab flexors.

Implantation of the FlareHawk7 Interbody Fusion System in PLIF:

The steps described above are the same except a PLIF surgical approach is used, and two total Implant assemblies are placed in parallel within the disc space in a straight anterior-posterior direction. Since two Implants are being placed, it is important to make sure enough space is available to expand both Implants.

SHIM, SHELL, & GUIDE PIN **CATALOG**

Part Numbers	Description
ASY-00370	**FlareHawk7 Implant Tray**
ASY-00367	**FlareHawk7 26mm Caddy**
FHTPCS0026C	Shell, Short 26mm, FlareHawk7
FHTPCT0026C	Shell, Tall 26mm, FlareHawk7
FHTPS20026S	Shim, 8mm or 11mm x 26mm, 0 Degree, FlareHawk7
FHTPS30026S	Shim, 9mm or 12mm x 26mm, 0 Degree, FlareHawk7
FHTPS40026S	Shim, 10mm or 13mm x 26mm, 0 Degree, FlareHawk7
FHTPS50026S	Shim, 11mm or 14mm x 26mm, 0 Degree, FlareHawk7
FHTPS10626S	Shim, 10mm or 12mm x 26mm, 6 Degree, FlareHawk7
FHTPS20626S	Shim, 11mm or 13mm x 26mm, 6 Degree, FlareHawk7
FHTPS30626S	Shim, 12mm or 14mm x 26mm, 6 Degree, FlareHawk7
ASY-00368	**FlareHawk7 30mm Caddy**
FHTPCS0030C	Shell, Short 30mm, FlareHawk7
FHTPCT0030C	Shell, Tall 30mm, FlareHawk7
FHTPS20030S	Shim, 8mm or 11mm x 30mm, 0 Degree, FlareHawk7
FHTPS30030S	Shim, 9mm or 12mm x 30mm, 0 Degree, FlareHawk7
FHTPS40030S	Shim, 10mm or 13mm x 30mm, 0 Degree, FlareHawk7
FHTPS50030S	Shim, 11mm or 14mm x 30mm, 0 Degree, FlareHawk7
FHTPS10630S	Shim, 10mm or 12mm x 30mm, 6 Degree, FlareHawk7
FHTPS20630S	Shim, 11mm or 13mm x 30mm, 6 Degree, FlareHawk7
FHTPS30630S	Shim, 12mm or 14mm x 30mm, 6 Degree, FlareHawk7
FHTPGP1A	Guide Pin, FlareHawk7 (gold)
ASY-00120	Insertion Instrument, FlareHawk7
FHTPCS0026TT	Shell, Short 26mm, TiHawk7
FHTPCT0026TT	Shell, Tall 26mm, TiHawk7
FHTPCS0030TT	Shell, Short 30mm, TiH7
FHTPCT0030TT	Shell, Tall 30mm, TiH7

INSTRUMENT **CATALOG**

Part Numbers	Description
ASY-00415	**FlareHawk7 Instrument Tray**
II-1-0045	Impact Cap
II-1-0015	Guide Pin Wrench
II-1-0372	Fixed T-Handle
ASY-00153	Short Obturator Impactor
ASY-00154	Tall Obturator Impactor
ASY-00122	Bone Funnel
ASY-00121	Bone Tamp

INSTRUMENT **CATALOG (Continued)**

Part Numbers	Description
ASY-00415	**FlareHawk7 Instrument Tray**
ASY-00133	Repeater, Bone Funnel
ASY-00132	Repeater, Bone Tamp
II-1-0434	Repeater, Crucible
II-1-0328	Fixed Hudson T-handle
ASY-00255	Shell Retriever
II-1-0005	Slap Hammer
ASY-00409	Shim Removal Tool
ASY-00418	FH7 26mm Lock Gauge
ASY-00422	FH7 30mm Lock Gauge
CMP-00698	7 mm x 29 mm, 0 Degree Shaver
CMP-00699	8 mm x 29 mm, 0 Degree Shaver
CMP-00700	9 mm x 29 mm, 0 Degree Shave+r
CMP-00701	10 mm x 29 mm, 0 Degree Shaver
CMP-00702	11 mm x 29 mm, 0 Degree Shaver
CMP-00703	12 mm x 29 mm, 0 Degree Shaver
CMP-00704	13 mm x 29 mm, 0 Degree Shaver
CMP-00705	14 mm x 29 mm, 0 Degree Shaver
II-1-0318	7mm Shaver
II-1-0319	8mm Shaver
II-1-0320	9mm Shaver
II-1-0321	10mm Shaver
II-1-0322	11mm Shaver
II-1-0323	12mm Shaver
II-1-0324	13mm Shaver
II-1-0325	14mm Shaver
II-1-0309	7mm Distractor
II-1-0310	8mm Distractor
II-1-0311	9mm Distractor
II-1-0312	10mm Distractor
II-1-0313	11mm Distractor
II-1-0314	12mm Distractor
II-1-0315	13mm Distractor
II-1-0316	14mm Distractor
ASY-00113	Expandable Trial, 0 Degree, FlareHawk7
CMP-01024	Tear Drop Handle

INSTRUCTIONS **FOR USE**

Please carefully read and understand this document in its entirety before using the FlareHawk® Interbody Fusion System. The components of the device are designed to be used in combination and function as a single unit. Failure to properly follow instructions may lead to patient injury and may result in improper functioning of the device.

Product Description

The Integrity Implants FlareHawk Interbody Fusion System is an expandable lumbar intervertebral body fusion device intended for use in the lumbosacral spine from L2 to S1 and is intended for intervertebral lumbar fusion. The FlareHawk implant consists of a Shell and a Shim component that are offered in a range of sizes to accommodate variation in patient anatomy. The Shell component is a rectangular frame with struts on all four sides that allow for insertion into the intervertebral body space in a non-expanded form, and subsequent expansion following the insertion of the Shim component. The Shim component has a tapered front end that inserts into and expands the Shell component to the desired vertical and horizontal dimensions. When fully inserted, the Shim locks within the Shell to provide structural stability for interbody fusion. An integrated "Core" in the Shell serves to anchor the delivery instrument during Shim insertion. Protrusions on the superior and inferior surfaces of the implant grip the adjacent vertebral endplates to resist expulsion. The FlareHawk implant is to be filled with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. Once implanted, the FlareHawk implant is designed to restore intervertebral disc height, provide anterior column support and maintain structural stability of the motion segment to facilitate intervertebral body fusion.

The FlareHawk Interbody Fusion System is a family of lumbar interbody fusion devices that includes FlareHawk9, FlareHawk7, FlareHawk11, TiHawk9, TiHawk7, and TiHawk11 devices.

The Integrity Implants FlareHawk Shells are manufactured from polyetheretherketone (PEEK) per ASTM F2026 and have integrated tantalum radiographic markers per ASTM F560. Additionally, the TiHawk9, TiHawk7, and TiHawk11 Shells are coated with a thin non-porous layer of Grade 2 commercially pure titanium that meets the chemical composition requirements of ASTM F67.

The FlareHawk Shim and Core are made from Titanium alloy per ASTM F136.

The Integrity Implants FlareHawk Interbody Fusion System includes sets of manual surgical instruments for delivery of the device

Indications for Use/Intended Use

The FlareHawk Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Contraindications

- Use of the FlareHawk system is contraindicated in patients with the following conditions:
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade I.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Active systemic infection.

- Infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Prior fusion at the level(s) to be treated.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any condition not described in the indications for use.
- Active local or systemic infection.
- Allergy to any device materials, including Polyetheretherketone, Tantalum, Titanium Alloy, or Commercially Pure Titanium.
- Irreversible bleeding disorder or coagulopathy.

Warnings

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture
- device or device component migration
- device subsidence
- loss of fixation
- non-union
- fracture of the vertebrae
- neurological injury, and
- vascular or visceral injury

The FlareHawk Interbody Fusion System should only be used by physicians with experience and training in spine surgery.

Interbody fusion devices for the treatment of degenerative conditions are designed to be full load bearing and withstand the loads associated with long-term use which could result from the presence of non-union or delayed union.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Precautions

- Read all instructions carefully prior to use. Failure to do so may result in possible patient injury.
- FlareHawk devices are provided either sterile or non-sterile. All devices provided non-sterile must be cleaned and sterilized by the user prior to use. All devices provided within sterilization trays are provided non-sterile. Refer to the product label for the sterility status of Individually packaged implants and instruments. Do not use devices labeled as sterile if the package is opened or damaged.
- A thorough understanding of the principles and techniques involved in spinal surgery procedures is essential to avoid possible injury to the patient. Only experienced spinal surgeons should perform the implantation of intervertebral fusion devices, having specific training in the use of this system, as this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Preoperative planning and patient anatomy should be considered when selecting implant size.
- Surgical implants must never be reused. An explanted implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which could lead to breakage.
- Adequately instruct the patient. Mental or physical impairment, which compromises or prevents a patient's ability to comply with necessary limitations or precautions, may place that patient at a particular risk during postoperative rehabilitation.
- FlareHawk implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating or migration in the MR environment.
- Postoperative care is important. The patient should be instructed of the limitations of physical activity such as lifting, twisting, or other excessive motions to reduce risk of excessive load bearing on the implant, and that failure to do so may compromise the implant integrity or delay the healing process. The surgeon should instruct the patient on the time frame required prior to returning to full physical activity.

Cleaning, Decontamination and Sterilization

Purpose

Unless supplied sterile, all devices should be cleaned and sterilized before use. This section provides recommended instructions for the cleaning and sterilization of non-sterile FlareHawk implants and accessory surgical instruments. This document is intended to assist health care personnel in the safe handling practices and effective reprocessing of these implants and instruments.

Scope

This instruction provides information on the care, cleaning, disinfection, maintenance and sterilization of single-use implants and reusable instruments and is applicable to the FlareHawk single-use implants and reusable accessory instruments that are supplied non-sterile but are intended to be used in a sterile state. FlareHawk implants and instruments are cleaned using either manual or a combination of a manual and automated process.

Precautions (Cleaning/Sterilization)

- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Dry soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.

Point of Use

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Note: Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (specifically including instruments with handles containing internal mechanisms including Integrity Implants FlareHawk Expandable Trials and Inserter Instruments (with cleaning slots), and more generally cannulated and tubular designs, etc.). These enzymatic solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

- For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning

- Where applicable assemblies of multiple devices and instruments should be disassembled for appropriate cleaning.
- Care should be exercised to avoid losing small screws and components.
- For instruments with turnable knobs and handles, prepare the instrument for cleaning by turning the knob or handle clockwise until stop is reached before cleaning and then repeat the cleaning procedure with the knob turned counterclockwise until stop is reached.

Note: For certain instruments, a handle may need to be temporarily attached to the instrument in order to turn the handle in both directions as instructed above.

Note: For instruments where a knob or handle position creates an opening between, leave the instrument in an open position.

Preparation of Cleaning Agents

- Neutral pH enzymatic and cleaning agents with low foaming surfactants are recommended.
- Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing.
- Only agents with proven efficacy (FDA cleared, VAH listed, or CE mark) should be used.
- Agents used during the validation of these processing instructions are: Steris®, Prolystica™ 2X Enzymatic Pre Soak and Cleaner, Prolystica™ Ultra Concentrate Neutral Detergent.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments and to ensure correct concentration.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Table 1: Cleaning/Disinfection Options

Method	Description
Manual	Enzymatic soak and scrub followed by sonication
Combination Manual/ Automated	Enzymatic soak and scrub followed by automated washer/ disinfector cycle

The manual method is effective for all devices and may be used when an automated option is not available.

Note: Manual cleaning may require onsite validation by the healthcare facility and appropriate procedures/ documentation should be in place to avoid human factor variability.

- The combination manual/automated method is preferred and can be used for all devices.

Manual Cleaning/Disinfection Instructions

- Completely submerge implants (within implant caddies) and instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
- Use a soft-bristled, nylon brush to gently scrub instrument devices until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
- Remove the devices from the cleaning solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes, slots and other difficult-to-reach areas.
- Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
- Rinse devices in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
- Repeat the sonication and rinse steps above.
- Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Combination Manual/Automated Cleaning and Disinfection Instructions

- Completely submerge the implants (within caddies) and instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak for 10 minutes.
- Use a soft nylon-bristled brush to gently scrub the devices until all visible soil has been removed. Particular attention must be given to crevices, lumens, slots, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. pipe cleaner).

Note: Use of a sonicator at 45-50 KHz will aid in thorough cleaning of devices. Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

- Remove devices from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
- Place instruments in a suitable washer/disinfector basket and

process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 2: Typical U.S. Automated Washer/ Disinfector Cycle for Surgical Devices

Step	Description
1	2 minute prewash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66 C/146-150 F)
6	15 second hot tap water rinse
7	10 second purified water rinse with optional lubricant (64-66 C/146-150 F)
8	7 to 30 minute hot air dry (116 C/240 F)

Inspection, Maintenance, Testing and Lubrication

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
- Visually inspect for cleanliness, and damage (including but not limited to, corrosion (rusting, pitting), discoloration, excessive scratches, flaking, crack and excessive wear).

Note: If damage or wear is noted that may compromise the function of the device, contact your representative for a replacement.

- Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations.

Note: Mineral oil or silicone lubricants should not be used because they 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

Note: These lubrication instructions are not applicable to air-powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer's instructions.

- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Where instruments form part of a larger assembly, check that the devices assemble readily with mating components. Dissembled devices should be reassembled prior to sterilization unless otherwise noted.

Sterile Packaging

Packaging individual devices

- Single devices should be packaged in a medical grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in the table below. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.
- Double-wrap the instruments for sterilization and handling with an FDA-cleared wrap using the envelope technique per ANSI/AAMI ST79.

Note: If sterilization wraps are used they must be free of detergent residues. Reusable wraps are not recommended.

Instrument trays and cases with defined, preconfigured layouts

- Areas designated for specific devices shall contain only devices specifically intended for these areas.
- Optional Integrity Implants devices should not be added to a preconfigured tray, caddie or case unless a dedicated universal space or compartment has been included in the design and the guidelines described below for trays and cases without defined layouts or universal spaces can be applied.
- Only devices manufactured and/or distributed by Integrity Implants should be included in Integrity Implants trays and caddies. These validated reprocessing instructions are not applicable to Integrity Implants trays and caddies that include devices that are not manufactured and/or distributed by Integrity Implants.
- Double-wrap the trays for sterilization and handling with an FDA-cleared wrap using the envelope technique per ANSI/AAMI ST79.

Sterilization Instructions

- See **Table 3** for recommended minimum sterilization parameters that have been validated by Integrity Implants to provide a 10^{-6} sterility assurance level (SAL).
- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the devices after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of

the instruments should also be recommended by the hospital.

- Moist heat/steam sterilization is the preferred and recommended method for Integrity Implants device sets.
- Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Devices should be properly prepared and packaged in trays, caddies and/or cases that will allow steam to penetrate and make direct contract with all surfaces.
- Ethylene oxide or gas plasma sterilization methods should not be used unless package inserts for the applicable product specifically provide instructions for sterilization using these methods.
- Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.

Table 3: Recommended Pre-Vacuum Steam Sterilization Parameters[1]

Temperature	Exposure Time	Minimum Dry Time[2]	Minimum Cool Down Time[3]
132°C/270°F	4 minutes	45 minutes	15 minutes

[1] This cycle is not to be used for the inactivation of prions.
[2] Drying times vary according to load size and should be increased for larger loads.
[3] Outside of chamber on a wire rack

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

Storage Instructions

- Sterile, packaged devices and sets should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Sterile device packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Note: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackaged and sterilized.

Note: If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the set resterilized.

Note: A surgical technique manual is available by contacting Integrity Implants.

INTEGRITYIMPLANTS

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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Symbol	Definition
REF	Reference number (Catalogue number)
LOT	Batch code (Lot number)
SN	Serial number
	Consult instructions for use
	Do not re-use / Single Use Only (Single Patient, Single-Use)
	Manufacturer
NON STERILE	Non-sterile
	Date of manufacture
STERILE R	Sterilizes using irradiation
	Do not use if package is damaged
	Use-by date

Symbol	Definition
Rx Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
IP	Intellectual Property: The labeled item or components within are protected under intellectual property according to US, state and federal law as well as foreign law. Detailed intellectual property information can be found at the website address.

FLAREHAWK7

LUMBAR INTERBODY FUSION SYSTEM

Bi-Directional Expansion | Minimal Insertion Profile | Maximum Graft Delivery

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